Pomalidomide

Healthcare Professional's Information Pack

UK

Version 1.0

Important Safety Information:
Healthcare professionals involved in the prescribing or dispensing of Pomalidomide must read and understand the information contained within this pack.

For complete safety information please refer to the Summary of Product Characteristics for pomalidomide, available at the Accord product site: accord-healthcare-products.co.uk

accord

Pomalidomide

Healthcare Professional's Information Pack

UK

This pack contains the information and materials needed for the prescribing and dispensing of Pomalidomide, including information about the Pregnancy Prevention Programme.

It is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing pomalidomide for ANY patient.

An easy reference guide is included at the back of your pack. This summarises the information for ongoing patient safety and the main steps in the Pomalidomide Pregnancy Prevention Programme process.

Pomalidomide is indicated:

- in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one treatment regimen including lenalidomide.
- in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to initiation of treatment.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis.

If pomalidomide is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this pack are carried out.

Version 1.0

MHRA approval date – July 2024

Information for Healthcare Professionals

This section contains information for prescribers and pharmacists, providing an overview of the pomalidomide Pregnancy Prevention Programme.

Pharmacy Registration Form

You will need this form to register your pharmacy in order to be able to obtain pomalidomide.

Information for Patients

This section contains information for your patients to take home and read, to reinforce the safety information you will provide to them during consultations.

Risk Awareness Forms

There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete these forms before prescribing pomalidomide to your patients.

Prescription Authorisation Forms

You will need to complete a Prescription Authorisation Form with every prescription for pomalidomide (completed forms must be sent to Accord).

Pregnancy Reporting Forms

Please report suspected and confirmed pregnancies, and foetal exposure. This section contains forms you can use.

Algorithm

Frequently Asked Questions

Important Contact Information

Information for Healthcare Professionals

This section contains information for prescribers and pharmacists, providing an overview of the pomalidomide Pregnancy Prevention Programme.

Pomalidomide
Pregnancy Prevention Programme

Information for Healthcare Professionals
Prescribing or Dispensing Pomalidomide

UK

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Risk Management contact details:
Tel: +44(0)7917920374
Email: rmpteam@accord-healthcare.com

This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the Pregnancy Prevention Programme (PPP). Please also refer to the summary of product Characteristics (SmPC), which can be found on the Accord product site: accord-healthcare-products.co.uk for further information.

Pomalidomide Pregnancy Prevention Programme (PPP):
If pomalidomide is taken during pregnancy it is expected to cause severe birth defect or death to an unborn baby. This programme is designed to make sure that unborn babies are not exposed to pomalidomide. It will provide you with information about how to follow the programme and explain your responsibilities.

Other side effect of pomalidomide:
A full list of all side effects, further information and recommended precautions can be found in the Pomalidomide SmPC.

Important information about the safe disposal of unwanted capsules and restrictions on donating blood during treatment is also included in this brochure.

This brochure will help you understand these problems and make sure you know what to do before prescribing and dispensing pomalidomide.

For your patients' health and safety, please read this brochure carefully. You must ensure that you patients fully understand what you have told them about pomalidomide and that they have provided written confirmation on the Risk Awareness Form, before starting treatment.

Contents

1.0 Introduction

1.1 Summary of the Pomalidomide Pregnancy Prevention Programme

This brochure contains the information needed for the prescribing and dispensing of pomalidomide including information about the Pregnancy Prevention Programme (PPP).

Pomalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Pomalidomide induced, in rats and rabbits, malformations similar to those described with thalidomide.

If pomalidomide is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Therefore, Pomalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met (please refer to sections 4.4 and 4.6 of the SmPC for further details).

• All men and all women of childbearing potential should undergo, at treatment initiation, counselling of the need to avoid pregnancy (this must be documented via a Risk Awareness Form)

• Patients should be capable of complying with the requirements of safe use of pomalidomide

• Patients must be provided with the appropriate Patient Brochure and Patient Pocket Information Card.

In order to obtain pomalidomide, it is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood the Additional Risk Minimisation Materials before prescribing or dispensing pomalidomide for **any** patient.

• Prescribers must complete the appropriate Risk Awareness Form with every patient before the first prescription is issued

• Pharmacies must register with Accord to be able to complete and approve Prescription Authorisation Forms (PAFs) and/or order and dispense pomalidomide. To do this, the pharmacist must either contact the Accord PV team using the details at the front of this

brochure, using the paper Pharmacy Registration Form or via the ePPP Portal – www.accord-eppp.co.uk.

• Every prescription for pomalidomide must be accompanied by a PAF, which must be completed by the prescriber and the pharmacist electronically via the ePPP portal or by completing the paper PAF and sending to Accord immediately.

• The Pharmacy Registration Form and Prescription Authorisation Form are in subsequent sections of this pack.

All patients should be given a Patient Brochure and a Patient Pocket Information Card to take home – these materials remind patients of the key educational information and risks of treatment and can be found in the Information for Patients section.

For women of childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.
Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test, must be within the 3 days prior to the date of the prescription.

For all other patients, prescriptions of pomalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription. Pharmacists are required to send copies of every PAF immediately after dispensing via the ePPP portal or sending to Accord (Email: rmpteam@accord-healthcare.com or Fax 01271 346106).

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of pomalidomide will only be allowed from pharmacies registered with Accord. Accord will not authorise supply of pomalidomide to pharmacies that are not registered. For pharmacies utilising a third party pharmacy to dispense the product to the patient, both the pharmacy completing/approving the PAF and the dispensing pharmacy are required to be registered with the Pomalidomide Pregnancy Prevention Programme.

The following are core requirements of the Pregnancy Prevention Programme:
• All healthcare professionals dispensing or prescribing pomalidomide must read the pomalidomide Healthcare Professional's Information Pack

• All pharmacies who dispense pomalidomide must agree to implement risk minimisation by registering with Accord's Pregnancy Prevention Programme

• If a third party pharmacy is only dispensing pomalidomide, the pharmacy completing and approving the PAFs must also register with the Accord Pregnancy Prevention Programme.

• Every prescription for pomalidomide must be accompanied by a PAF, which can be completed electronically via the ePPP portal or by completing the paper PAF and a copy must be sent to Accord.

1.2 Overview of the Healthcare Professionals' Information pack

All of the Pomalidomide Pregnancy Prevention Programme materials are contained within this pack and, the additional Risk Minimisation Materials (aRMMs) are also available as individual materials. Additional hard copies can be obtained by contacting Accord by using the contact details displayed on the front of this brochure.

You must ensure that your patients fully understand what you have told them about pomalidomide before starting the treatment.

This brochure contains key information for healthcare professionals and contains the following:

- Educational information
- Therapy management advice to avoid foetal exposure to pomalidomide
- A distribution control system
- Safety advice of relevance to all patients
- Process for follow-up of effectiveness of the measures described in this pack
- Process for reporting adverse events and pregnancy in patients treated with pomalidomide

This Healthcare Professional's Information Pack also contains an Algorithm and Risk Awareness Forms for obtaining consent.
The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential are set out in the attached Algorithm.

1.3 Teratogenicity: Potential or Actual Foetal Exposure to Pomalidomide

Pomalidomide must never be used by women who are able to become pregnant unless they follow the Pomalidomide Pregnancy Prevention Programme described in the pack (section 2.0).

Since pomalidomide may be present in the semen of males patients, all male and female patients must both follow effective contraceptive measures.

If a female patient or female partner of a male patient misses, or is suspected to have missed her period, or has any abnormality in menstrual bleeding, or suspects she is pregnant, then:

- Pomalidomide must be discontinued immediately, if a female patient
- The woman must have a pregnancy test
- If the pregnancy test is positive, the woman should be referred to a physician experienced in teratology for further evaluation and counselling.

Any positive pregnancy test or suspected foetal exposure to pomalidomide must be reported immediately to the Medicines and Healthcare products Regulatory Agency (MHRA) and to Accord. In this instance you must:

- Stop treatment immediately, if a female patient
- Refer the patient/partner to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Accord immediately by contacting Medical Information on 01271 385257; Email medinfo@accord-healthcare.com. Please also complete the Pregnancy Reporting Form included in this pack and send it to the Accord medical Information department. Accord will wish to follow up with you on the progress of all pregnancies.

You can report the suspected pregnancy online using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid yellow cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the omission on Human Medicines (CHM) free phone line: 0800 731 6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

1.4 Safety Advice Relevant to all Patients

In addition to information about the Pregnancy Prevention Programme, this brochure contains important advice for healthcare professionals about how to minimise the risk of adverse events during treatment with pomalidomide.

For further information about the appropriate use and safety profile of pomalidomide, please refer to the SmPC, which can be found on the Accord product site: accord-healthcare-products.co.uk.

You must complete electronically via the ePPP portal or on paper and send every PAF immediately to Accord, for ALL patients, regardless of indication or risk category. This is an absolute requirement so that Accord can fulfil regulatory obligations to monitor PPP adherence and off-label usage.

Accord is obliged to provide anonymous reports on this data to the MHRA, to assess the effectiveness of risk minimisation activities and will not be able to comply if pharmacies do not complete their PAFs or provide to Accord immediately. If sending paper PAFs, use the following contact details:

Fax: 01271 346106
Email: rmpteam@accord-healthcare.com

If you wish to use e-mail, please scan the completed paper form and e-mail it as an attachment. An editable PDF file is available on Accord product site or the ePPP portal. Please keep a copy of the paper Prescription Authorisation Forms for your records.

2.0 Therapeutic Management Advice to Avoid Foetal Exposure

2.1 Women of Non-childbearing Potential (WNCBP)

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice:
• Age ≥ 50 years and naturally amenorrhoeaic for ≥ 1 year. Please note amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential
• Premature ovarian failure confirmed by a specialist gynaecologist
• Previous bilateral salpingo-oophorectomy, or hysterectomy
• XY genotype, Turner syndrome, uterine agenesis.

A female patient is considered to have childbearing potential unless she meets at least one of the above criteria. Prescribers are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

If a patient does not meet at least one of above criteria, but the prescriber considers the patient to be of nonchildbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from Accord via email: rmpteam@accord-healthcare.com). The following information is required to assess whether a patient, who does not meet at least one of the above criteria, can be treated as a women of non-childbearing potential:

• DOB and Initials of the Patient
• Details of why the prescriber considers the patient to be of non-childbearing potential
• Background to why a deviation has been requested.

2.2 Women of Childbearing Potential (WCBP)

Women of childbearing potential must never take pomalidomide if they are:
• Pregnant
• Able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided.

Women of childbearing potential must understand the need to avoid pregnancy, and these patients must be adequately informed regarding the use of effective contraceptive measures every time a prescription is issued.

Women of childbearing potential (even if they have amenorrhoea) must use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after pomalidomide therapy finished, and even in case of dose interruption. This must be followed unless the patient commits to absolute and continuous abstinence, confirmed on a monthly basis.

If your patient is not established on effective contraception, she must be referred to an appropriately trained healthcare professional for contraceptive advice before initiating contraception.

The following can be considered to be examples of suitable methods of contraception:
• Implant
• Levonorgestrel-releasing intrauterine system (IUS)
• Medroxyprogesterone acetate depot
• Tubal sterilisation
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and IUSs are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia.

Insertion of copper-releasing intrauterine devices is not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise patients with neutropenia or thrombocytopenia.

Your patient should be advised that if a pregnancy does occur whilst she is receiving pomalidomide, she must stop treatment immediately and immediately inform her prescriber.

If your patient needs to change or stop her method of contraception during her pomalidomide therapy, she must understand the need to discuss this first with:

- The physician prescribing her method of contraception.
- The physician prescribing her pomalidomide.

If a woman of childbearing potential has sexual contact without using an effective contraception method while taking pomalidomide or believes for any reason that she may be pregnant, she must stop treatment and consult her prescriber immediately.

Pregnancy Testing

For women of childbearing potential a pregnancy test must be performed prior to issuing a prescription. This may be embarrassing for some patients and may need to be handled sensitively. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

Women of childbearing potential (even if they have amenorrhoea) must have a medically supervised negative pregnancy test prior to issuing a prescription (with a minimum sensitivity of 25 mIU/ml) once she has been established on contraception for at least 4 weeks, at least every 4 weeks during therapy (this includes dose interruptions) and at least 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This includes those women of childbearing potential who confirm absolute and continued abstinence.

Patients who are being prescribed the appropriate contraceptive method by the physician, should inform their physician about pomalidomide treatment. Patients should be advised to inform you if a change or stop of method of contraception is needed.

A pregnancy test must be performed immediately if a patient misses her period, if there is any abnormality in menstrual bleeding, if she has heterosexual intercourse without using a contraceptive method, or if she suspects she is pregnant.

If a female patient has a positive pregnancy test, then:

- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Accord immediately by contacting Medical Information on 01271 385257; Email medinfo@accord-healthcare.com. Please also complete the Pregnancy Reporting Form included in this pack and send it to the Accord medical Information department. Accord will wish to follow up with you on the progress of all pregnancies.

You can report the suspected pregnancy online using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid yellow cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the omission on Human Medicines (CHM) free phone line: 0800 731 6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

2.3 Men

In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided. Therefore your male patients must be counselled at Risk Awareness on the risks and benefits of pomalidomide therapy including the risk of birth defects, other side effects and important precautions associated with pomalidomide therapy. Inform your patient which are the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen. As a precaution, and taking into account special populations with potentially prolonged elimination time such as renal impairment, all male patients taking pomalidomide, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruptions and for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential and has no contraception.

Patients should be instructed that if their partner does become pregnant whilst he is taking pomalidomide or within 7 days after he has stopped taking pomalidomide, he should inform his prescriber immediately. The partner should inform her physician immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice.

Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of pomalidomide.

You can report the suspected pregnancy online using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid yellow cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the omission on Human Medicines (CHM) free phone line: 0800 731 6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

2.4 Advice for all Patients

Your patient must be informed not to donate blood during or within 7 days after stopping treatment. If your patient discontinues therapy, they must return any unused pomalidomide to the pharmacy.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

They must also understand that their pomalidomide is only for them, and it:

- Must not be shared with anyone else, even if they have similar symptoms
- Must be stored away safely so no one else could take the capsules by accident
- Must be kept out of the reach and sight of children.

3.0 Healthcare Professional Obligations

Healthcare Professionals have specific obligations that must be followed when prescribing or dispensing pomalidomide, which are:

Prescriber: You must ensure that

- Your patient is fully educated on the risks of pomalidomide
- You complete the appropriate 'Risk Awareness Form' with your patient before the first prescription is issued
- You provide the patient with a 'Patient Pocket Information Card', Patient Brochure and a copy of the 'Risk Awareness Form'
- If relevant, your patient is using the appropriate method of contraception
- Female patients of childbearing potential undergo a pregnancy test, which must be negative, before every prescription that you issue
- You complete a PAF with every prescription
    - This includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription
- You prescribe pomalidomide in accordance with the measures described in this brochure and the SmPC, which can be found on the accord product site: accord-healthcare-products.co.uk

Pharmacist: You must ensure that

- Your pharmacy is registered with the Pomalidomide Pregnancy Prevention Programme. Registration will be valid for 2 years
- Pomalidomide is only dispensed if the prescription is accompanies by a PAF. This includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription
    - You check and validate the PAF prior to dispensing pomalidomide
    - You dispense pomalidomide in accordance with the measures described in this brochure
    - You send a copy of the PAF immediately to Accord Healthcare
    - You remind patients of the key education messages each time pomalidomide is

dispensed.

3.1 Information for Prescribers

3.1.1 Patient and Healthcare Professional education

As the prescriber, you play a central role in ensuring that pomalidomide is used safely and correctly.

Most importantly, you will be helping to ensure that your patients understand the risks involved in taking pomalidomide and that they are aware of their responsibilities in preventing foetal exposure to the drug. In addition, you may need to help your patients understand the process involved in the pomalidomide Pregnancy Prevention Programme. This will help to prevent any delays in your patients receiving their treatment.

If you refer your patient to a fertility expert (e.g. obstetrician or gynaecologist) for further contraceptive advice or pregnancy testing counselling, it is your responsibility to ensure that the fertility expert is aware of the Pomalidomide Pregnancy Prevention Programme.

3.1.2 Patient Counselling and Education

Because of the different levels of risk, you will need to communicate different information to men, women and children. You must ensure that your patient understands the information before they complete their section of the Risk Awareness Form.

Please make use of the Patient Brochure and Patient Pocket Information Card to help explain the relevant information. Copies of the brochure are contained in your 'Healthcare Professional's Information Pack', and you patient should take these materials home to read in their own time or with a relative. Further copies can be obtained by using the contact details displayed on the front of this brochure.

3.1.3 Prescribing pomalidomide

3.1.3.1 Maximum Prescription Lengths

- Prescriptions for women of childbearing potential can be for a maximum duration of treatment of 4 weeks according to the approved indications dosing regimens and prescriptions for all other patients can be for a maximum duration of 12 weeks. Do not dispense to a woman of childbearing potential unless the pregnancy test is negative and was performed within 3 days prior to the prescription.
- For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

3.1.3.2 Initial Prescription

Before issuing the initial prescription, you must:

• Counsel the patient on the safe use of pomalidomide in accordance with the measures described in this brochure and the SmPC, which can be found on the Accord product site: accord-healthcare-products.co.uk
• Obtain their written confirmation (using the correct Risk Awareness Form) that they have received and understood this information, and provide the patient with a copy
• Provide the patient with a Patient Brochure and a Patient Pocket Information Card
- If using the online ePPP portal, you must complete all necessary fields and provide the patient with only the prescription
- If using the paper system a PAF must be provided to the patient with each pomalidomide prescription and this will contain:
  – Patient initials, date of birth and diagnosis
  – Prescriber name, signature and date
  – Patient risk category (women of childbearing potential, women of non-childbearing potential or male)
  – Confirmation that they have received counselling on the safe use of pomalidomide
  – For women of childbearing potential, the pregnancy test date and result

On completion of the PAF, it is transferred to the pharmacy along with the accompanying prescription and the pharmacy will check this form prior to dispensing pomalidomide. If the prescriber has completed via the online ePPP portal, the pharmacist will automatically receive a notification via the same system.

Once the PAF has been checked for completeness, a copy of the PAF must be sent to Accord, if a paper PAF is used.

3.1.3.3 Repeat of Subsequent Prescriptions

The patient must return to a prescriber for every repeat prescription of pomalidomide.

3.2 Information for Pharmacists

As a pharmacist you play an important role in ensuring that pomalidomide is used safely and correctly. Pomalidomide will only be supplied to pharmacies that have complete an 'Pomalidomide Pregnancy Prevention Programme, Pharmacy Registration Form' and returned this form to Accord. Pharmacy that only complete and approve PAFs and do not order or dispense pomalidomide will still need to complete the Pharmacy Registration Form (PRF).

3.2.1 Dispensing pomalidomide

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to order and dispense pomalidomide are registered with Accord. For pharmacies utilising a third party pharmacy to dispense the product to the patient, both the pharmacy completing and approving the PAF and the dispensing pharmacy are required to be registered for the Pomalidomide Pregnancy Prevention Programme. Registration involves receiving Additional Risk Minimisation Materials and completing the registration electronically via the ePPP

portal or by e-mailing, faxing or posting to Accord a signed paper Pharmacy Registration Form to indicate agreement and compliance with the content.

Dispensing of pomalidomide will only be allowed from pharmacies registered with Accord. Accord will not authorise purchase and supply of pomalidomide to pharmacies not registered with Accord.

Pomalidomide is supplied to pharmacies registered with Accord's Risk Minimisation Program known as the UK Pregnancy Prevention Programme (PPP) only for the purpose of dispensing the product by the PPP registered pharmacy to the patient.

In order to be registered, the Chief Pharmacist or appointed deputy of the institution wishing to dispense must agree to implement the use of a PAF.

Along with each pomalidomide prescription, prescribers must complete the PAF and for paper PAFs, instruct the patient to provide this to their pharmacy. You must only dispense pomalidomide if the prescriber has annotated this form correctly. When completing the online ePPP portal or paper PAF, it asks the prescriber to confirm:

- The patient's diagnosis
- The patient's risk category
- If of childbearing potential that adequate contraception is in place and the date of the last negative pregnancy test, which must be within the **3 days** prior to the date of the prescription
- If male, counselling regarding the use of condoms has taken place
- That a Risk Awareness Form has been completed by the patient
- That the prescriber has read and understood the contents of this Healthcare Professional's Information Pack.

When completing the online ePPP portal or paper PAF, it asks the pharmacist to confirm:

- That the PAF has been completed in full by the prescriber
- That the supply dispensed is no more than a 4-week supply for a WCBP and no more than a 12-week supply for male and WNCBP patients
- That dispensing for women of childbearing potential is taking place within **7 days** of the prescription date
- That the pharmacist has read and understood the contents of this Healthcare Professional's Information Pack.

For women of childbearing potential, prescriptions for pomalidomide should be limited to 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test, must be within the 3 days prior to the date of the prescription.

If using the paper system, the prescription for pomalidomide must be accompanied by a paper PAF and this must be retained for a minimum of 2 years, a copy of this form must be sent to Accord.

3.2.2 Dispensing Advice

• Please ensure that you dispense pomalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles
• For each prescription, dispense a maximum of a 4-week supply for women of childbearing potential or a 12-week supply for all other patients
• Please educate all pharmacists within your pharmacy about the dispensing procedures for pomalidomide
• Instruct patients to return any unused pomalidomide to the pharmacy. Pharmacies must accept any unused pomalidomide returned by patients for destruction and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

4.0 Follow-up Assessment of the Effectiveness of the Programme

The terms of the pomalidomide Marketing Authorisation require Accord to assess the effectiveness of the Pregnancy Prevention Programme in order to ensure that all reasonable steps are being taken to reduce the risk of foetal exposure to pomalidomide.

Accord is therefore obliged to perform audits at regular intervals and to report appropriately anonymous and aggregated results to the MHRA. Accord will conduct the audit from all of the completed PAFs received.

Pharmacies must complete via the online ePPP portal or send a copy of every completed paper PAF immediately after dispensing to Accord, then Accord will be able to conduct the pharmacy audit using these forms (a manual self-audit by pharmacies will not be required). It is critical, therefore, that PAFs are completed accurately, and that pharmacies thereby assist Accord to audit the effectiveness of the Pregnancy Prevention Programme as implemented in the UK.

Accord is obliged to provide the anonymised reports on the data received from the PAFs to the regulatory agencies. The reports are used to assess the effectiveness of risk minimisation activities and Accord will not be able to comply if pharmacies do not complete their PAFs or provide ALL their PAFs to Accord immediately.

If sending paper PAFs, use the following contact details:
Email: rmpteam@accord-healthcare.com
Fax: 01271 346106
Please keep a copy of the PAFs for your records

Electronic copies of the PAF can also be found at accord-healthcare-products.co.uk

5.0 Safety Advice relevant to all Parties

The following section contains advice to Healthcare Professionals about how t minimise the risk of thrombocytopenia and cardiac failure associated with the use of pomalidomide. Please refer to SmPC (sections 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects) for complete information on all the risks associated with pomalidomide.

In general, most adverse reactions occurred more frequently during the first 2 to 3 months of treatment. Please note that the posology, adverse event profile and recommendations outlined herein, particularly in respect of neutropenia and thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

5.1 Risk of thrombocytopenia and cardiac failure with pomalidomide

5.1.1 Thrombocytopenia

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide.

It is therefore encouraged to monitor complete blood counts (CBC) – including platelet count – weekly for the first 8 weeks and monthly thereafter.

A dose modification or interruption may be required. Patients may require use of blood product support and/or growth factors.

Thrombocytopenia can be managed with dose modifications and/or interruptions. Recommended dose modifications during treatment and restart of treatment with pomalidomide are outlined in the table below:

Dose Modification or Interruption Instructions

Toxicity	Dose Modification
Thrombocytopenia • Platelet count <25 x 10^9/L	Interrupt pomalidomide treatment, follow CBC weekly
• Platelet Count return to ≥50 x 10^9/L	Resume pomalidomide treatment at one dose lower than previous dose

• For each subsequent drop <25 x 10^9/L • Platelet Count return to ≥50 x 10^9/L	Interrupt pomalidomide treatment Resume pomalidomide treatment at one dose level lower than previous dose

CBC – Complete Blood Count

To initiate a new cycle of pomalidomide, the platelet count must be ≥50 x 10^9/L.

5.1.2 Cardiac Failure

Cardiac events, including congestive cardiac failure, pulmonary oedema and atrial fibrillation (see Section 4.8 of the SmPC), have been reported, mainly in patients with pre-existing cardiac disease or cardiac risk factors. Appropriate caution should be exercised when considering the treatment of such patients with pomalidomide, including periodic monitoring for signs or symptoms of cardiac events (see Section 4.4 of the SmPC).

5.2 Safety and Off-Label Use

Please note that the posology, adverse event profile and recommendations outlined above, relate to the use of pomalidomide within its licensed indication. Pomalidomide must always be used according to the Pregnancy Prevention Programme described in this pack – these precautions must be followed, irrespective of the treatment setting, including the indication for treatment. It is essential that the patient's diagnosis is entered on the PAF – this will allow an assessment of the clinical usage of pomalidomide, which is important for ongoing monitoring of safety.

5.3 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

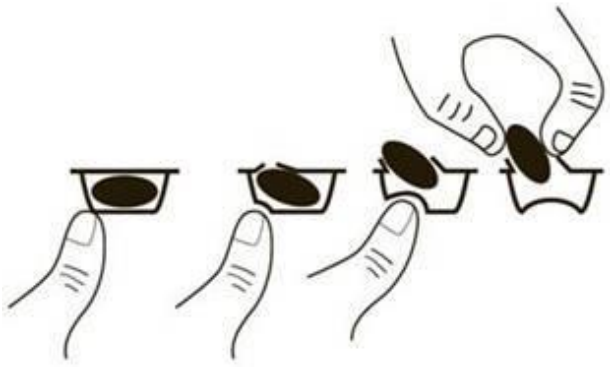
Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children.

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who

are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer below for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a healthcare professional or caregiver

• If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
• Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule)
• Use proper technique when removing gloves to prevent potential skin exposure (see below)
• Place gloves in sealable plastic polyethylene bag and dispose according to local requirements
• Wash hands thoroughly with soap and water after removing gloves.
• Patients should be advised never to give the medicinal product to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure

• If outer carton is visibly damaged – **Do Not Open**
• If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – **close outer carton immediately**
• Place the product inside a sealable plastic polyethylene bag
• Return unused pack to the pharmacist for safe disposal as soon as possible.

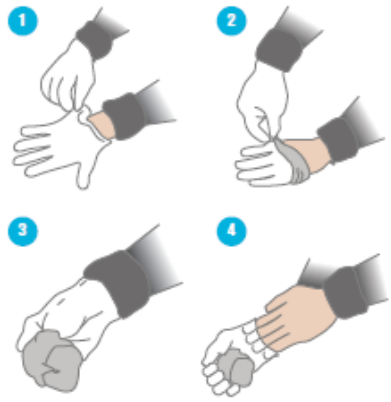
If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

• If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
• Wear disposable gloves to clean up the powder
• Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it
• Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products

• Wash your hands thoroughly with soap and water after removing the gloves
• Please report to Accord (Tel: 01271 385257 Email: medinfo@accord-healthcare.com).

If the contents of the capsule are attached to the skin or mucous membranes
• If you touch the drug powder, please wash exposed area thoroughly with running water and soap
• If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

Proper Technique for Removing Gloves:
• Grasp outside edge near wrist (1)
• Peel away from hand, turning glove inside-out (2)
• Hold in opposite gloved hand (3)
• Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4)
• Peel off from inside, creating a bag for both gloves.
• Discard in appropriate container
• Wash your hands with soap and water thoroughly.



5.4 Blood Donation

Patients should not donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with pomalidomide.

6.0 Reporting Adverse Events, suspected and confirmed pregnancies, and foetal exposures

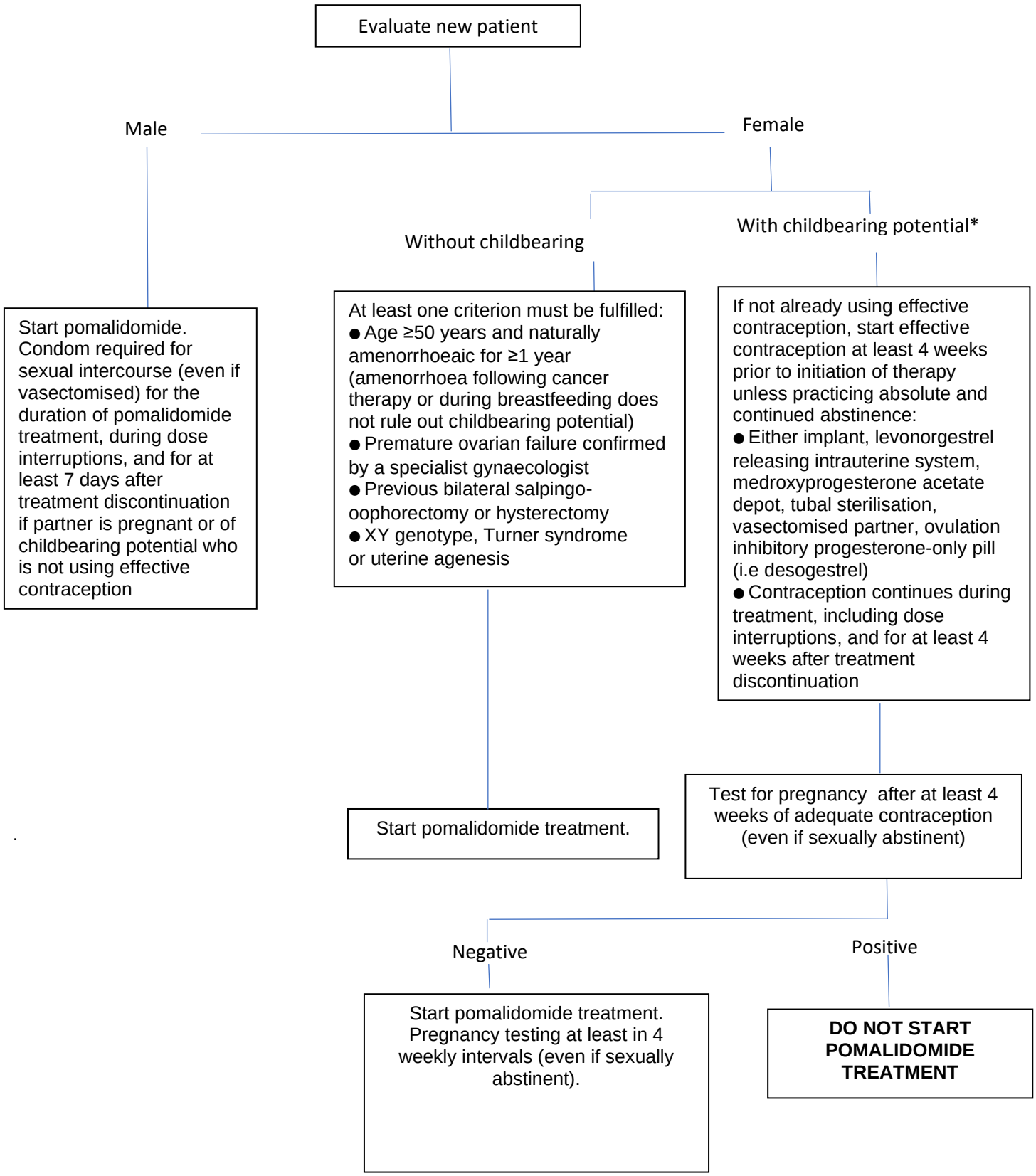
The safe use of pomalidomide is of paramount importance.

Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Pregnancy Reporting forms are included in this pack and should be forwarded to Accord (Tel: 01271 385257; Email: medinfo@accord-healthcare.com).

You can report suspected pregnancies and adverse events online using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

7.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



8.0 Contact Details

Risk management:
For information and questions on the Risk Management of Accord products, the Pregnancy Prevention Programme, pharmacy registrations or the online ePPP portal www.accord-eppp.co.uk please contact Accord PV team:
Tel: +44 (0)7917920374
Fax: 01271 346106
Email: rmpteam@accord-healthcare.com.

Medical Information:
For reporting of adverse events and any suspected pregnancies please contact Accord medical information team:
Tel: 01271 385257
Email: medinfo@accord-healthcare.com.

You can report the suspected pregnancy online using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid yellow cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the omission on Human Medicines (CHM) free phone line: 0800 731 6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Distributor:
For product delivery enquires please contact –
Healthnet Homecare (UK) Ltd
Units 1 & 2 Orbit Business Park, Swadlincote, DE11 0WU
Email: wholesaleorders@healthnethomecare.co.uk
Tel: 08000 833 060

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Tel: +44(0)7917920374 Fax: 01271 346106

Pharmacy Registration Form

You will need this form to register your pharmacy in order to be able to obtain pomalidomide.

Pomalidomide Pharmacy Registration Form – Page 1 of 2

Must be completed by the Chief or appointed Deputy Pharmacist (PRINT IN BLOCK CAPITALS)

Please fill in all requested information completely *Fields are mandatory, incomplete information will result in delay.
All Pharmacies completing and approving pomalidomide Prescription Authorisation Forms (PAFs) and/or ordering and dispensing pomalidomide are required to complete this form.

*This form is being completed by (select as appropriate)	Chief Pharmacist ☐	Deputy Pharmacist ☐
*Name of Pharmacist	First Name:	Surname:
Pharmacist GPhC / PSNI Registration Number:		
Pharmacist Contact Details	Telephone:	E-mail:

DISPENSING PHARMACY ADDRESS

NHS Trust Name / Private Group / Other (enter full name):		
*Pharmacy Name:		
Pharmacy GPhC / PSNI Registration Number (if applicable):		
*Address line 1:		
Address line 2:		
*Town / City:	County:	*Postcode:
*Pharmacy Contact Details	Telephone:	E-mail:

DELIVERY ADDRESS (IF DIFFERENT)

*Address line 1:		
Address line 2:		
*Town / City:	County:	*Postcode:

***PHARMACY AGREEMENT**

By registering the above-named pharmacy to complete and approve PAFs and/or order and dispense pomalidomide, I agree to implement and ensure compliance with the risk minimisation measures associated with the Pregnancy Prevention Programme (PPP) for pomalidomide and adhere to the following requirements:	Select Box to Acknowledge Agreement
1. Acknowledge receipt of the pomalidomide Healthcare Professionals' Information Pack (HCPIP) (the Additional Risk Minimisation Materials (ARMMs)) provided.	☐
2. Confirm that all pharmacists who complete and approve PAFs and/or dispense pomalidomide will have read and understood the pomalidomide HCPIP and will ensure that the pregnancy prevention measures have been implemented before dispensing pomalidomide	☐
3. Check that each pomalidomide prescription is provided with an associated pomalidomide PAF, completed electronically via the ePPP portal or by using the paper PAF.	☐
4. Check the PAF for completeness and/or request any missing information from the Prescriber and/or patient and complete the Dispensing Pharmacist section of the PAF, prior to dispensing pomalidomide.	☐
5. For **women of childbearing potential (WCBP)**, check that the PAF confirms: a. the WCBP has been counselled/reminded about the teratogenic risk and has been on at least one effective method of contraception for at least 4 weeks b. the WCBP has had a negative pregnancy test within the 3 days prior to the prescription date c. the dispensing of pomalidomide is within 7 days of the prescription date d. the supply of treatment is no more than 4 weeks.	☐
6. For **male patients**, check that the PAF confirms: a. the patient has been counselled/reminded about the teratogenic risk and the requirement to use a condom if sexually active with a pregnant woman or a WCBP not using effective contraception b. the supply of treatment is no more than 12 weeks.	☐
7. For **women not of childbearing potential (WNCBP)**, check the supply of treatment is no more than 12 weeks.	☐
8. For pharmacies not completing PAFs via the ePPP, a copy of each completed paper PAF must be sent to Accord immediately after each pomalidomide prescription is dispensed. Pharmacies should retain the original paper PAF at the pharmacy premises for a minimum of 2-years.	☐
9. Should an institution utilise its own electronic systems (or paper PAF) to implement the risk minimisation measures associated with the PPP, ensure that all data fields at a minimum, correspond to those that are included in the Accord PAF. Justification for use, together with the proposed PAF should be provided to Accord for review and subsequent approval by the MHRA. **A copy of each completed PAF must be sent immediately to Accord.**	☐
10. Ensure on receipt of pomalidomide, it is only dispensed to the patient by the pharmacy registered with Accord, to fulfil the requirements of the PPP for pomalidomide. **Wholesaling is strictly prohibited.**	☐
11. Notify Accord **immediately** of changes in Chief Pharmacist or appointed Deputy Pharmacist, including their corresponding contact details in order to ensure appropriate registration of the pharmacy to order and dispense Pomalidomide.	☐

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Pomalidomide Pharmacy Registration Form – Page 2 of 2

Must be completed by the Chief or appointed Deputy Pharmacist (PRINT IN BLOCK CAPITALS)

*PHARMACIST DECLARATION	
1. I acknowledge this registration to complete and approve PAFs and/or order and dispense pomalidomide is valid for 2 years only, after which I am required to re-register the above-named pharmacy, should I wish to continue to complete and approve PAFs and/or order and dispense pomalidomide.	❑
2. I understand during the period of registration, if I am unable to fulfil requirements 1-11, the above named-pharmacy will be de-registered by Accord. I will be unable to order any further pomalidomide and required to go through the registration process again, following any necessary remedial action(s).	❑
3. I understand that my personal data will be processed by Accord, for the purposes of administering the PPP for pomalidomide.	❑
4. I understand the information supplied to Accord on PAFs will be used to provide anonymised aggregate annual reports to the Medicines and Healthcare products Regulatory Agency (MHRA) to assess the implementation of the PPP.	❑

*Pharmacist Signature:	*Signature Date:	D	D	M	M	M	Y	Y	Y	Y

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Email the completed forms to Accord at rmpteam@accord-healthcare.com, alternatively fax the forms to 01271 346106

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK

Information for Patients

This section contains information for your patients to take home and read, to reinforce the safety information you will provide to them during consultations.

Pomalidomide

Pregnancy Prevention Programme

Information for Patients Taking Pomalidomide

UK

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Accord contact details:
Tel: 01271 385 257
Email: medinfo@accord-healthcare.com

This brochure contains information about:

Preventing harm to unborn babies: If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby

Pomalidomide Pregnancy Prevention Programme: This programme is designed to ensure that unborn babies are not exposed to pomalidomide. It will provide you with information about what to expect from your treatment, and explain the risks and your responsibilities.

Pomalidomide must never be used by a woman who is pregnant. In addition, it is important to know that pomalidomide passes into men's semen and is expected to cause severe birth defects or death to an unborn baby. So if you are a male patient, there is a risk if you have unprotected sex with a woman who can become pregnant.

This brochure will help you understand what to do before, during and after taking pomalidomide.

This brochure will not give you information about multiple myeloma, you should ask your prescriber if you have any questions.

Warning: Severe life-threatening birth defects. If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Pomalidomide must never be used by women who are pregnant, as just one capsule can cause severe birth defects.

Pomalidomide must never be used by women who are able to become pregnant unless they follow the Pomalidomide Pregnancy Prevention Programme.

For complete information on all possible side effects please read the Package Leaflet that comes with your pomalidomide capsules.

This brochure also contains important information about the requirement to avoid blood donation during treatment, the safe handling of pomalidomide and the safe disposal of unused pomalidomide capsules.

For your own health and safety, please read this brochure as well the Package Leaflet that comes with your medicine carefully. If you do not understand something, please ask your prescriber for further explanation.

Contents

Introduction

Pomalidomide is used to treat adults with a type of cancer called 'multiple myeloma'. Pomalidomide works in a number of different ways:

- by stopping the cancer cells developing
- by stimulating the immune system to attack the cancer cells
- by stopping the formation of blood vessels supplying the cancer cells.

Pomalidomide is either used with:

- two other medicines called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment – including lenalidomide

Or

- one other medicine called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments – including lenalidomide and bortezomib.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life threatening birth defects. Therefore, if pomalidomide is taken during pregnancy, a teratogenic effect is expected.

Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans. Therefore, precautions must be taken to avoid exposure to pomalidomide in an unborn baby.

This brochure is part of the Pomalidomide Pregnancy Prevention Programme, which is necessary because if pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

This brochure contains important information about the Pomalidomide Pregnancy Prevention Programme. You must read the information carefully and before starting treatment you should:

• Understand the risks of pomalidomide treatment.

• Understand the guidelines for taking pomalidomide safely, including how to prevent pregnancy.

• Understand what to expect during your initial and follow-up consultations with your prescriber.

• Your prescriber will explain to you the risks of pomalidomide treatment and specific instructions that you must follow.

• Please make sure that you understand what your prescriber has told you before starting Pomalidomide.

If you don't understand something, please ask your prescriber for further explanation.

Pomalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of pomalidomide is that if taken during pregnancy, it can cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means pomalidomide must never be taken by:
• Women who are pregnant
• Women who could become pregnant,
unless they follow the Pomalidomide Pregnancy Prevention Programme

Pomalidomide and Other Possible Side Effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber or pharmacist if you would like more information and refer to the Package Leaflet. Most side effects are temporary and can be easily prevented and treated. The most important thing is to be aware of what to expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

You can report suspected pregnancies and side effects online using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/d or search for MHRA Yellow Card in the Google Play or Apple App Store.
Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800 731 6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Side effects and suspected pregnancies should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Before and during the treatment with pomalidomide you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your prescriber should ask you to have a blood test:

- before treatment
- every week for the first 8 weeks of treatment
- at least every month after that for as long as you are taking pomalidomide.

As a result of these tests, your prescriber may change your dose of pomalidomide or stop your treatment. The prescriber may also change the dose or stop the medication because of your general health.

Pregnancy Prevention Programme

You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant, as **pomalidomide is expected to be harmful to an unborn child.**

Before starting treatment your prescriber will ask you to read and sign a Risk Awareness Form.

What should you tell your prescriber before taking pomalidomide:

- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, as pomalidomide is expected to be harmful to an unborn child
- If you think you are able to become pregnant and need advice on effective contraception
- If you are breastfeeding
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called 'thalidomide' or 'lenalidomide'
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing to any other ingredient in pomalidomide capsules. Ask your pharmacist for advice
- If you have had a heart attack, have heart failure, have difficulty breathing, if you smoke, have high blood pressure or high cholesterol levels
- If you have a history of thrombosis (blood clots)
- If you are taking or have recently taken any other medicines, including medicines brought without a prescription
- If you have a high total amount of tumour throughout your body, including you bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome
- If you have or have had neuropathy (nerve damage causing tingling or pain in your hands or feet
- If you have or have ever had hepatitis B infection. Treatment with pomalidomide may cause the hepatitis B virus to become active again in patient who carry the virus, resulting in a recurrence of the infection. Your prescriber should check whether you have ever had hepatitis B infection
- If you experience or have experienced in the past a combination of any of the following symptoms: rash on face or extended rash, red skin, high fever, flu-like symptoms, enlarged lymph nodes, signs of severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis (TEN) or Steven-Johnson Syndrome (SJS).

Childbearing Potential Assessment

Do not take pomalidomide if you are pregnant or think you may be pregnant or are planning to become pregnant – this is because **pomalidomide is expected to be harmful to an unborn child.** Unless you fall into one of the following categories you must follow the contraceptive advice
presented in the next section:

• You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during breast feeding, then there is still a chance you could become pregnant)

• Your womb has been removed (hysterectomy)

• Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy)

• You have premature ovarian failure, confirmed by a specialist gynaecologist

• You have the XY genotype, Turner syndrome or uterine agenesis.

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant. Every woman who is able to become pregnant even if they are not planning to, must follow the precautions detailed in this section.

Contraception Methods for Women of Childbearing Potential

You must never take pomalidomide if:

- You are pregnant
- You are a woman who is able to become pregnant, even if you are not planning to become pregnant.

Pomalidomide is expected to be harmful to the unborn child

- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant, and ensuring you are not pregnant during treatment. Before starting the treatment, you should ask your prescriber if you are able to become pregnant, even if you think this is unlikely
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity, you will have pregnancy tests under the supervision of your prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruption and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilization)
- If you are able to become pregnant, unless you commit to absolute and continuous abstinence confirmed on a monthly basis, you must use at least one effective method of contraception for a least 4 weeks before starting treatment, throughout the duration of your treatment (including does interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with pomalidomide. It is essential therefore that you discuss this with your prescriber
- If you suspect you are pregnant at any time whilst taking pomalidomide or in the 4 weeks after stopping treatment, you must stop pomalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialized or experienced in teratology for evaluation and advice
- Inform the prescriber of you contraception that you are on pomalidomide
- Inform your prescriber of pomalidomide if you have changed or stopped the method of contraception
- Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching menopause may still be able to become pregnant
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for you **NOT** to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- You should start your pomalidomide treatment as soon as possible after having a

negative pregnancy test result and having received pomalidomide

Contraception to Prevent Pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment

Or

- Agree you will not engage in sexual activity with a male partner starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment. You will be asked to confirm this every month.

Not all types of contraception are suitable during pomalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

Contraception Methods for Males

Pomalidomide is expected to be harmful to the unborn child

• In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for your partner NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 7 days after you stop pomalidomide

• Ask your prescriber to inform you of which are the effective contraceptive methods that your female partner can use

• Pomalidomide passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use condoms throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop pomalidomide even if you have had a vasectomy

• If your partner does become pregnant whilst you are taking pomalidomide or within 7 days after you have stopped taking pomalidomide, you should inform your prescriber immediately and your partner should also consult her physician immediately

• You should not donate blood or semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment

Women of Non-Childbearing Potential

Pomalidomide is expected to be harmful to the unborn child.

• In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become Pregnant

• You should never share pomalidomide with anyone else

• You should always return any unused capsules to the pharmacist for safe disposal as soon as possible

• You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment

• For additional information, please refer to the Package Leaflet.

Pomalidomide Treatment

Before Starting Your Treatment

Your prescriber will talk to you about what to expect from your treatment, and explain the risks and your responsibilities. If there is anything you do not understand, please ask your prescriber to explain it further.

Before starting treatment your prescriber will ask you to read and sign a Risk Awareness Form, which confirms that while taking pomalidomide:

• You understand the risks of birth defects

• You agree not to become pregnant

• You understand the other important safety messages. Your prescriber will keep one copy for your medical file and provide one copy to you.

Safety Information For All Patients

- You must never take pomalidomide if you are allergic to pomalidomide or to any of the other ingredients contained in the capsule
- You should never share pomalidomide with anyone else
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible
- You should not donate blood during treatment, during dose interruption, or for a least 7 days after stopping treatment
- If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist
- For additional information, please refer to the package leaflet

Receiving Your Prescription

Your prescriber may provide you with a 'Prescription Authorisation Form (PAF)' that must be provided to the pharmacist, which confirms that all of the Pomalidomide Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your pomalidomide. Alternatively, your prescriber may complete the PAF electronically, in which case the PAF will be sent directly to the pharmacist.

For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply, provided you have had a valid negative pregnancy test within 3 days prior to your prescription date and you must have the medication dispensed within 7 days of the prescription date.

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

You will need to see your prescriber each time you need a repeat prescription.

How to Take your Medication

Your pharmacist can provide you help and advice on taking your medications. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medications.

• Your prescriber will prescribe a dose of pomalidomide suited to you

• Your prescriber may adjust your dose depending on the result of blood tests and any side effects you may experience

• Do not take more capsules than your doctor has prescribed. If in doubt, ask your prescriber or pharmacist for advice

- The capsules should not be opened, broken or chewed

• Pomalidomide capsules should be swallowed whole, with a glass of water and can be taken with or without food

• Pomalidomide can be taken at any time of day but it should be taken at approximately the same time each day

What to do if you have taken more than the prescribed dose of pomalidomide:

If you accidentally take too many capsules, contact your prescriber immediately.

Taking other medicines

Please tell your prescriber or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different prescriber or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking pomalidomide and dexamethasone.

How to store pomalidomide safely

- Keep your pomalidomide in a safe place out of sight and reach of children
- Keep you pomalidomide capsules in the original carton
- Do not use after the expiry date stated on the blister and carton

End of Treatment Requirements

After completing your pomalidomide treatment, it is important that:

• You return any unused pomalidomide capsules to your pharmacist

• You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

• Continue using your method of contraception method for at least a further 4 weeks

• Your prescriber will perform a final pregnancy test after at least 4 weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

• If you have been using an effective method of contraception, you must continue doing so for at least 7 days

• If your female partner has been using an effective method of contraception, she must continue doing so for at least 4 weeks

• Do not donate semen or sperm for at least 7 days.

Points to Consider for Handling the Medicinal Product: for Patients, Family Members and Caregivers

Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children.

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).

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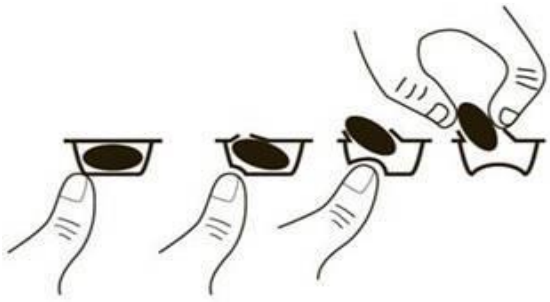
Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a family member and/or caregiver:

• If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule

• Wear disposable gloves when handling product and or packaging (i.e. blister or capsule)

• Use proper technique when removing gloves to prevent potential skin exposure (see over)

• Place gloves in sealable plastic polyethylene bag and dispose according to local requirements

• Wash hands thoroughly with soap and water after removing gloves.

- Do not give pomalidomide to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure:
• If outer carton is visibly damaged – **Do Not Open**

• If blister strips are damaged or leaking or capsules are noted to be damaged or leaking
– **Close outer carton immediately**
– Place the product inside a sealable plastic polyethylene bag
– Return unused pack to the pharmacist for safe disposal as soon as possible.

If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection:
• If capsules are crushed or broken, dust containing drug substance may be released.

- Avoid dispersing the powder and avoid breathing the powder

• Wear disposable gloves to clean up the powder

• Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling clean the area thoroughly with soap and water and dry it

• Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products

• Wash your hands thoroughly with soap and water after removing the gloves

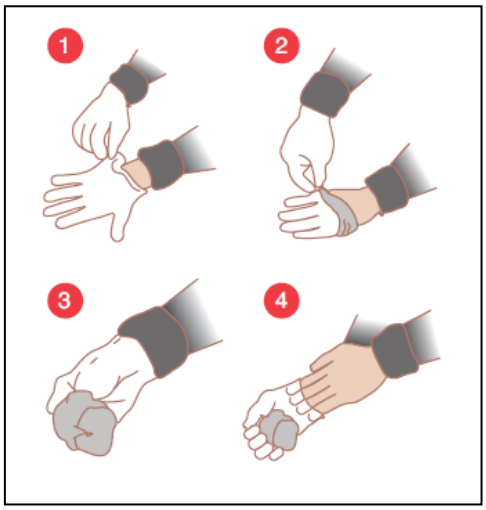
• Please report to the prescriber and/or pharmacist immediately.

If the contents of the capsule are attached to the skin or mucous membranes:
• If you touch the drug powder, please wash exposed area thoroughly with running water and soap

• If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

Proper Technique for Removing Gloves:

- Grasp outside edge near wrist (1)
- Peel away from hand, turning glove inside-out (2)
- Hold in opposite gloved hand (3)
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4)
- Peel off from inside, creating a bag for both gloves
- Discard in appropriate container
- Wash your hands with soap and water thoroughly.



Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

Check List

Please use this check list to confirm that you have understood all of the important information regarding your pomalidomide treatment.

All patients

TICK	Yes, I have understood that I should never share pomalidomide with anyone else.
TICK	Yes, I have understood that I should always return any unused capsules to the pharmacist for safe disposal as soon as possible.

TICK	Yes, I have received and understood all the information on the risks of birth defects associated with taking pomalidomide.
TICK	Yes, I have received and understood all the information on the risks of other side effects associated with taking pomalidomide.
TICK	Yes, I have understood that I must not donate blood during treatment (including dose interruptions) and for at least 7 days after stopping treatment.
TICK	Yes, I understand that I need to sign the Risk Awareness Form before starting treatment.

Male patients

TICK	Yes, I have understood the need to use condoms during treatment during dose interruption and for at least 7 days after stopping pomalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
TICK	I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping pomalidomide.

Female patients who can become pregnant

TICK	Yes, I will use one effective method of contraception for at least 4 weeks before starting pomalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped pomalidomide treatment.
TICK	Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every 4 weeks during treatment and at least 4 weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Tel: 01271 385257

Emergency Contact information:

Emergency Prescriber Contact:
Telephone number during office hours:
Telephone number after office hours:

For complete information on the side effects of pomalidomide patients should read the package leaflet and Healthcare Professionals should read the Summary of Product Characteristics.

MHRA approval date July 2024
BBBB8285

back

Pomalidomide

This patient is on pomalidomide.

Information for Patients:

- You MUST tell your prescriber immediately if you experience any symptoms that cause concern
- You MUST inform your prescriber immediately if you suspect you or your female partner is pregnant.

front

Information for Patients and Healthcare Professionals

Pomalidomide is an immunomodulator and is an expected human teratogen therefore:

- Women of childbearing potential must use at least one effective method of contraception and male patients with pregnant partners or partners of childbearing potential not using effective contraception must always use condoms (even if man has had a vasectomy)
- Women of childbearing potential must have regular pregnancy tests to ensure that they are not pregnant, except in the case of confirmed tubal sterilisation.
- If a female patient or female partner of a male patient suspects they are pregnant they must contact their **doctor immediately**

inside left

Information for Healthcare Professionals:

Prescription details

Prescription date:	DD	MM	YYYY
Has the patient received counselling?	Yes ☐	No ☐	
Childbearing potential assessment:	WCBP / WNCBP / Male		
This patient is receiving pomalidomide for treatment of: ☐ Multiple Myeloma ☐ Relapsed and Refractory Multiple Myeloma			

inside right

Risk Awareness Forms

There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete these forms before prescribing pomalidomide to your patients.

Pomalidomide
Pregnancy Prevention Programme (PPP)

Women of Childbearing Potential
Risk Awareness Form

UK
Version 1

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme
via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Risk Awareness Form for counselling the patient to ensure the patient is fully informed about the safe use of pomalidomide

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female patient of childbearing potential prior to the initiation of their pomalidomide treatment. This form must be completed by a physician with expertise in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of pomalidomide. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of pomalidomide. Pomalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

This form should be retained with their medical records, and a copy provided to the patient.

It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Pomalidomide must not be taken during pregnancy since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.
If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:																						
Patient Last Name:																						

Date of Birth:	*DD*	*MM*	*YYYY*	Counselling Date:	*DD*	*MM*	*YYYY*

Did you inform your patient		WCBP
1	Of the need to avoid foetal exposure	*Tick*
2	That if she is pregnant or plans to be, she must not take pomalidomide	*Tick*
3	That she understands the need to avoid pomalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment	*Tick*
4	That if she needs to change or stop using her method of contraception she should inform (a) the physician prescribing her contraception that she is taking pomalidomide (b) the physician prescribing pomalidomide that she has stopped or changed her method of contraception	*Tick*
5	Of the need for pregnancy tests (i.e. before treatment) at least every 4 weeks during treatment and after treatment	*Tick*
6	Of the need to stop pomalidomide immediately upon suspicion of pregnancy	*Tick*
7	Of the need to contact their doctor immediately on suspicion of pregnancy	*Tick*
8	To not share the medicinal product with any other person	*Tick*
9	That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide	*Tick*
10	That they should return the unused capsules to the pharmacist at the end of treatment	*Tick*

Can you confirm your patient

1	Was referred to a contraceptive consultant, if required?	Y/N
2	Is capable of complying with contraceptive measures?	Y/N
3	Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	Y/N
4	Has a negative pregnancy test before staring treatment even if absolute and continued abstinence?	Y/N

Contraceptive Referral

Contraceptive referral required			YES	NO
Contraceptive referral made	DD	MM	YYYY	
Contraceptive consultation conducted on	DD	MM	YYYY	

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	Tick
Levonorgestrel-releasing intrauterine system (IUS)	Tick
Medroxyprogesterone acetate depot	Tick
Tubal sterilisation	Tick
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	Tick
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	Tick
Committed to complete and absolute abstinence	Tick

Pregnancy Test

Date of last negative pregnancy test	DD	MM	YYYY

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUOUS ABSTINENCE, AND PREGNANCY TEST IS NEGATIVE.

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential.

I will comply with my obligations and responsibilities as the prescriber of pomalidomide.
I confirm I have informed the patient (data subject) that their personal data will be communicated to Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance) in line with article 13 of the General (EU) 2016/679 Data Protection Regulation.

Prescriber First Name:				
Prescriber Last Name:				
Prescriber signature:		Date:	DD	MM YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	Patient initials
I understand that severe birth defects are expected to occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	Patient initials
I understand that I must not take pomalidomide if I am pregnant or plan to become pregnant.	Patient initials
I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in the case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	Patient initials
I understand that if I need to change or stop my method of contraception I will discuss this first with the physician prescribing my contraception and the physician prescribing my pomalidomide.	Patient initials
I understand that before starting the pomalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	Patient initials
I understand that I must immediately stop taking pomalidomide and inform my prescriber if I become pregnant while taking this drug; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	Patient initials
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the pomalidomide Patient Booklet and understand the contents, including the information about other possible important health problems (side effects) associated with the use of pomalidomide.	Patient initials
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I understand that even if I have amenorrhoea I must comply with advise on contraception.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Pomalidomide Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data collected on the Prescription Authorisation Form (PAF) will be processed by Accord-UK Ltd, as the marketing authorisation holder of pomalidomide for the purpose of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please visit our privacy policy available on our website www.accord-healthcare.com

Patient signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Signed:		Name: (print)		Date:	DD	MM	YYYY

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK
Phone: +44 (0)7917920374
Website: www.accord-healthcare.co.uk

Approved by MHRA: July 2024
BBBB8292

Pomalidomide
Pregnancy Prevention Programme (PPP)

Male Risk Awareness Form

UK
Version 1

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme
via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Risk Awareness Form for counselling the patient to ensure the patient is fully informed about the safe use of pomalidomide

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each male prior to the initiation of their pomalidomide treatment. This form must be completed by a physician with expertise in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of pomalidomide. It is mandatory that male patients receive counselling and education to be made aware of the risks of pomalidomide.

The form should be retained with their medical records, and a copy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Pomalidomide must not be taken during pregnancy since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.
If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:																							
Patient Last Name:																							

Date of Birth:	DD	MM	YYYY	Counselling Date:	DD	MM	YYYY

Did you inform your patient

	Male
1 Of the need to avoid foetal exposure	Tick
2 To not share the medicinal product with any other person	Tick
3 That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide	Tick
4 That they should return the unused capsules to the pharmacist at the end of treatment	Tick
5 That pomalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy)	Tick
6 That if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom	Tick
7 That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide	Tick

Pregnancy Prevention

The patient confirms that:	
They will use a condom during intercourse with a woman of childbearing potential	Tick
Their female partner is using an effective method of pregnancy prevention	Tick
Their female partner is of non-childbearing potential	Tick
They are committed to complete and absolute abstinence	Tick

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential. I will comply with my obligations and responsibilities as the prescribing physician of pomalidomide.

Prescriber First Name:																							
Prescriber Last Name:																							

Prescriber signature:		Date:	DD	MM	YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	Patient initials
I understand that severe birth defects can occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	Patient initials
I understand that pomalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop pomalidomide even if I have had a vasectomy.	Patient initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the Pomalidomide Patient Booklet and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	Patient initials
I understand that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	Patient initials
I know that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after discontinuation of pomalidomide.	Patient initials
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about which are effective contraceptive methods that my female partner can use.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Pomalidomide Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data collected on the Prescription Authorisation Form (PAF) will be processed by Accord-UK Ltd, as the marketing authorisation holder of pomalidomide for the purpose of managing the Pregnancy Prevention Programme.

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Should you have any queries in relation to the use of your personal data please visit our privacy policy available on our website www.accord-healthcare.com

Patient signature:		Date:	*DD*	*MM*	*YYYY*

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Signed:		Name: (print)		Date:	*DD*	*MM*	*YYYY*

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK
Phone: +44 (0)7917920374
Website: www.accord-healthcare.co.uk

Approved by MHRA: July 2024
BBBB8291

Pomalidomide
Pregnancy Prevention Programme (PPP)

Women of Non-Childbearing Potential
Risk Awareness Form

UK
Version 1

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
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Risk Awareness Form for counselling the patient to ensure the patient is fully informed about the safe use of pomalidomide

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each woman of non-childbearing potential prior to the initiation of their pomalidomide treatment. This form must be completed by a physician with expertise in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of pomalidomide. It is mandatory that woman of non-childbearing potential receive counselling and education to be made aware of the risks of pomalidomide.

The form should be retained with their medical records, and a copy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Pomalidomide must not be taken during pregnancy since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.
If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name:																							
Patient Last Name:																							

Date of Birth:	DD	MM	YYYY	Counselling Date:	DD	MM	YYYY

Did you inform your patient

	WNCBP
1. To not share the medicinal product with any other person	
2. That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide	
3. That they should return the unused capsules to the pharmacist at the end of treatment	

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential.
I will comply with my obligations and responsibilities as the prescribing physician of pomalidomide.

Prescriber First Name:																							
Prescriber Last Name:																							

Prescriber Signature:				Date:	DD	MM	YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	Patient initials
I understand that severe birth defects are expected to occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	Patient initials
I have read the Pomalidomide Patient Booklet and understand the contents, including the information about other possible important health problems (side effects) associated with the use of pomalidomide.	Patient initials
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for a least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Pomalidomide Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data collected on the Prescription Authorisation Form or ("PAF") will be processed by Accord-UK Ltd, as the marketing authorisation holder of pomalidomide for the purpose of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please visit our privacy policy available on our website www.accord-healthcare.com

Patient signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Signed:		Name: (print)		Date:	*DD*	*MM*	*YYYY*

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK
Phone: +44 (0)7917920374
Website: www.accord-healthcare.co.uk

Approved by MHRA: July 2024
BBBB8293

Prescription Authorisation Forms

You will need to complete a Prescription Authorisation Form with every prescription for pomalidomide (completed forms must be sent to Accord).

A guide to Completing the Prescription Authorisation Form (PAF)

The guide will help you complete the pomalidomide Prescription Authorisation form (PAF).
For prescribers and pharmacists not utilising the ePPP portal, this form is available. A PAF must be completed each time you prescribe pomalidomide for all patients.

Instructions for prescribers

1. Print your name clearly.
   Print the name of the Supervising Physician (if you are a non-physician prescriber), i.e. the physician experienced in managing immunomodulatory drugs and supervising treatment.
   Print the full name of the prescribing Institution where the patient is being treated.
   Print your telephone number/bleep number.
2. Tick the appropriate box specifying whether this is an initial or subsequent prescription.
3. Enter the patient's initials.
4. Enter the patient's date of birth.
5. Enter the date of the patients prescription.
6. Please specify the total supply prescribed for this prescription. Also specify the strength of capsule and total number of capsules dispensed.
7. Please specify whether pomalidomide is being used to treat a licensed or an unlicensed indication. If unlicensed, please specify the indication in the form.
8. Please specify whether the patient is a woman of childbearing potential, male or woman of non-childbearing potential.
9. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescription date). If this is not the case pomalidomide must not be dispensed.
10. Complete this section appropriately to indicate that counselling and appropriate use of contraception has occurred. This is a requirement of the Pregnancy Prevention programme.
11. You must sign, date and print your name to declare that the information provided on the form is accurate, complete and in accordance with the requirements of the Pregnancy Prevention programme.

Instructions for pharmacists

12. Enter your full name and the full name and postcode of the pharmacy.
13. If applicable, complete the Third-Party Dispensing Pharmacy/Home Delivery information.
14. Please specify the date pomalidomide was dispensed. Prior to dispensing, please check that all relevant sections of the form have been completed by the prescriber.

a. Counselling and contraception measures must be in place
b. Prescription must be accompanied by an accurately completed PAF
c. For women of childbearing potential pomalidomide can only be dispensed within 7 days of the prescription date
d. Only a maximum of 4 weeks supply for women of childbearing potential, or a maximum of 12 weeks supply for all other patients, of pomalidomide can be dispensed at any one time.

15. Please specify whether there were any changes made to the PAF. To indicate any changes/corrections made to the PAF, please add your initials and date against the changes.

Pomalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY pomalidomide prescription for ALL patients in accordance with the Pomalidomide Pregnancy Prevention Programme, mandated by the Medicines and Healthcare products Regulatory Agency (MHRA). Email all completed Prescription Authorisation Forms to rpmteam@accord-healthcare.com for fax to 01271 346106 immediately after dispensing.

TO BE COMPLETED BY PRESCRIBING HEALTHCARE PROFESSIONAL

1. Prescriber Stamp or Contact Details

Full Name of Prescriber	First Name:	Surname:
Supervising Physician	First Name:	Surname:
Full Name of Prescribing Institution:		Postcode:
Prescriber Telephone / Bleep Number:		

2. Please verify if this PAF is for an initial or subsequent prescription of pomalidomide – only tick one box
☐ Initial prescription (full teratogenic risk counselling) ☐ Subsequent prescription (reminder teratogenic risk)

3. Patient Initials (First/Middle/Last): **4. Patient Date of Birth** (DD/MMM/YYYY): D D M M M Y Y Y Y

5. Prescription Date (DD/MMM/YYYY): D D M M M Y Y Y Y

6. Total Supply Prescribed: ☐ 4-weeks ☐ 8-weeks ☐ 12-weeks Other – please enter number of weeks:
Capsule strength prescribed Total number of capsules prescribed

7. Indication:
☐ Licensed
☐ Unlicensed – specify indication below:

8. Patient Risk Category:
☐ Woman of Childbearing Potential (WCBP) (Please proceed to section 9, 10a & 11)
☐ Male (Please proceed to section 10b & 11)
☐ Woman of Non-Childbearing Potential (WNCBP) (Please proceed to section 11)

9. WCBP Pregnancy Test Date* (DD/MMM/YYYY): D D M M M Y Y Y Y

Pregnancy Test Result:* ☐ Negative ☐ Positive* ☐ Inconclusive* ☐ Test not done* – Please provide reason

* DO NOT prescribe if positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation) or pregnancy test date is more than 3 days before prescription date.

10. Patient Counselling: Only tick box(es) for applicable patient risk category

10a. WCBP:
☐ The WCBP has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and the need to avoid pregnancy.
☐ The WCPB has been on at least one effective method of contraception for at least 4 weeks (includes male partners who have had a vasectomy, which must be confirmed by two negative semen tests; as well as absolute and continuous abstinence from heterosexual intercourse confirmed on a monthly basis).

10b. Male:
☐ The male patient has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and understands the need to use a condom, if involved in sexual activity with a pregnant woman or a WCBP not using effective contraception (even if the male patient has had a vasectomy).

11. Prescriber's Declaration: As the Prescriber, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

11a. Prescriber Signature: **11b. Signature Date** (DD/MMM/YYYY): D D M M M Y Y Y Y

APPROVAL TO BE COMPLETED BY PHARMACIST

12. Pharmacy Stamp or Contact Details:

Full Name of Pharmacist	First Name:	Surname:
Full Name of Pharmacy:		Postcode:

13. Name and postcode of Third-Party Dispensing Pharmacy / Home Delivery (Please complete only if applicable)

Name:	Postcode:

14. Dispensing Date (DD/MMM/YYYY): D D M M M Y Y Y Y

DO NOT dispense if pregnancy test is positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation), or as follows:
For WCBP, do not dispense pomalidomide unless negative pregnancy test was conducted within 3 days of the prescription date and dispensing is taking place within 7 days of the prescription date. No more than a 4-week supply to a WCBP and a 12-week supply to a male patient or a WNCBP should be dispensed.

15. Pharmacist Confirmation
Information which was not completed by the Prescriber and is required to fulfil the PPP for pomalidomide has been received by the Pharmacist via other routes, or verbally confirmed by the Prescriber and / or patient and documented in this form. **Note:** To indicate any changes / corrections made in the PAF, please add your initials and date against the changes ☐ Yes ☐ Not Applicable

16. Accord Pomalidomide brand dispensed? ☐ Yes ☐ No

17. Pharmacist's Declaration: As the Pharmacist, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the PPP for pomalidomide.

17a. Pharmacist Signature: **17b. Signature Date** (DD/MMM/YYYY): D D M M M Y Y Y Y

16. As there are multiple pomalidomide brands available please confirm if the Accord Pomalidomide brand is being dispensed. The Accord PAF should only be used for Accord Pomalidomide.
17. You must sign, date and print your name to declare that the information provided on this form is accurate, complete and in accordance with the Pregnancy Prevention Programme. Email all completed Prescription Authorisation Forms to rmpteam@accord-healthcare.com or fax to 01271 346106 immediately after dispensing.

Further information and materials are available from Accord.
Telephone: +44(0)7917920374
E-mail: rmpteam@accord-healthcare.com
Fax – 01271 346106

Electronic copies are also available on the Accord Product site - www.accord-healthcare-products.co.uk

Alternatively, PAFs can be completed via the ePPP.
For further information, please contact:
Tel: 07917920374
Email: rmpteam@accord-healthcare.com

Approved by MHRA: July 2024
BBBB8289

Pomalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY pomalidomide prescription for ALL patients in accordance with the Pomalidomide Pregnancy Prevention Programme, mandated by the Medicines and Healthcare products Regulatory Agency (MHRA). Email all completed Prescription Authorisation Forms to rmpteam@accord-healthcare.com for fax to 01271 346106 immediately after dispensing.

TO BE COMPLETED BY PRESCRIBING HEALTHCARE PROFESSIONAL

1. Prescriber Stamp or Contact Details

Full Name of Prescriber	First Name:	Surname:
Supervising Physician	First Name:	Surname:
Full Name of Prescribing Institution:		Postcode:
Prescriber Telephone / Bleep Number:		

2. Please verify if this PAF is for an initial or subsequent prescription of pomalidomide – only tick one box

☐ Initial prescription (full teratogenic risk counselling) ☐ Subsequent prescription (reminder teratogenic risk)

3. Patient Initials (First/Middle/Last): | **4. Patient Date of Birth** (DD/MMM/YYYY): D D M M M Y Y Y Y

5. Prescription Date (DD/MMM/YYYY): D D M M M Y Y Y Y

6. Total Supply Prescribed: ☐ 4-weeks ☐ 8-weeks ☐ 12-weeks Other – please enter number of weeks:

Capsule strength prescribed Total number of capsules prescribed

7. Indication:

☐ Licensed

☐ Unlicensed – specify indication below:

8. Patient Risk Category:

☐ Woman of Childbearing Potential (WCBP) (Please proceed to section 9, 10a & 11)

☐ Male (Please proceed to section 10b & 11)

☐ Woman of Non-Childbearing Potential (WNCBP) (Please proceed to section 11)

9. WCBP Pregnancy Test Date* (DD/MMM/YYYY): D D M M M Y Y Y Y

Pregnancy Test Result:* ☐ Negative ☐ Positive* ☐ Inconclusive* ☐ Test not done* – Please provide reason

* DO NOT prescribe if positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation) or pregnancy test date is more than 3 days before prescription date.

10. Patient Counselling: Only tick box(es) for applicable patient risk category

10a. WCBP:

☐ The WCBP has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and the need to avoid pregnancy.

☐ The WCPB has been on at least one effective method of contraception for at least 4 weeks (includes male partners who have had a vasectomy, which must be confirmed by two negative semen tests; as well as absolute and continuous abstinence from heterosexual intercourse confirmed on a monthly basis).

10b. Male:

☐ The male patient has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and understands the need to use a condom, if involved in sexual activity with a pregnant woman or a WCBP not using effective contraception (even if the male patient has had a vasectomy).

11. Prescriber's Declaration: As the Prescriber, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

11a. Prescriber Signature: | **11b. Signature Date** (DD/MMM/YYYY): D D M M M Y Y Y Y

APPROVAL TO BE COMPLETED BY PHARMACIST

12. Pharmacy Stamp or Contact Details:

Full Name of Pharmacist	First Name:	Surname:
Full Name of Pharmacy:		Postcode:

13. Name and postcode of Third-Party Dispensing Pharmacy / Home Delivery (Please complete only if applicable)

Name: Postcode:

14. Dispensing Date (DD/MMM/YYYY): D D M M M Y Y Y Y

DO NOT dispense if pregnancy test is positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation), or as follows:

For WCBP, do not dispense pomalidomide unless negative pregnancy test was conducted within 3 days of the prescription date and dispensing is taking place within 7 days of the prescription date. No more than a 4-week supply to a WCBP and a 12-week supply to a male patient or a WNCBP should be dispensed.

15. Pharmacist Confirmation

Information which was not completed by the Prescriber and is required to fulfil the PPP for pomalidomide has been received by the Pharmacist via other routes, or verbally confirmed by the Prescriber and / or patient and documented in this form. **Note:** To indicate any changes / corrections made in the PAF, please add your initials and date against the changes ☐ Yes ☐ Not Applicable

16. Accord Pomalidomide brand dispensed? ☐ Yes ☐ No

17. Pharmacist's Declaration: As the Pharmacist, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the PPP for pomalidomide.

17a. Pharmacist Signature: | **17b. Signature Date** (DD/MMM/YYYY): D D M M M Y Y Y Y

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Pregnancy Reporting Forms

Please report suspected and confirmed pregnancies, and foetal exposure. This section contains forms you can use.

Pomalidomide
Pregnancy Report Form

UK

Pregnancy reports for pomalidomide must be sent to Accord Medical information IMMEDIATELY

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Date of awareness: D D M O N Y Y Y Y

Patient Data

Sex of Patient: ○ Female ○ Male

○ Pregnancy of Patient

○ Pregnancy of Patient's Partner **OR**

○ Exposure of a Pregnant Female (complete information below)

Pregnant Woman's Initials (F, M, L): | Date of Birth: D D M O N Y Y Y Y | Age:

Patient Initials (F, M, L): (Who received drug) | Date of Birth: D D M O N Y Y Y Y | Age:

Drug Name:

Date of First Dose: D D M O N Y Y Y Y | Date of Last Dose: D D M O N Y Y Y Y

Pregnancy Initially Diagnosed By:

○ Home Urine Test

○ Office Urine Test

○ Serum Test

Date of Pregnancy Test: D D M O N Y Y Y Y | Last Menstrual Period: D D M O N Y Y Y Y

Female is Currently: ____ weeks pregnant **OR** ○ No longer Pregnant ○ Unknown

Female has Elected to: ○ Carry Pregnancy to Term | Expected Date of Delivery: D D M O N Y Y Y Y

○ Terminate Pregnancy | Date Performed or Pending: D D M O N Y Y Y Y

Reporter's Information:

Reporter's Name: | Date: D D M O N Y Y Y Y

Reporter's Contact Information/ Address:
○ GB
○ Northern Ireland | Reporter's Signature:

Reporter's Phone Number:

Reporter's Email Address: | Reporter's Fax Number:

Patient's Prescribing Physician's Information:

Physician's Name: | Date: D D M O N Y Y Y Y

Physician's Contact Information/ Address:
○ GB
○ Northern Ireland | Physician's Signature:

Physician's Phone Number:

Physician's Email Address: | Physician's Fax Number:

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UK

Pregnancy reports for pomalidomide must be sent to Accord Medical information IMMEDIATELY

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com

Background Information on Reason for Pregnancy

Was patient erroneously considered not to be of childbearing potential?	○ Yes	○ No
If yes, state reason for considering not to be of childbearing potential		
• Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year *amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential	○ Yes	○ No
• Premature ovarian failure confirmed by a specialist gynaecologist	○ Yes	○ No
• Previous bilateral salpingo-oophorectomy, or hysterectomy	○ Yes	○ No
• XY genotype, Turner syndrome, uterine agenesis.	○ Yes	○ No
Indicate from the list below what contraception was used		
• Implant	○ Yes	○ No
• Levonorgestrel-releasing intrauterine system (IUS)	○ Yes	○ No
• Medroxyprogesterone acetate depot	○ Yes	○ No
• Tubal sterilisation (specify below)	○ Yes	○ No
○ Tubal ligation	○ Yes	○ No
○ Tubal diathermy	○ Yes	○ No
○ Tubal chips	○ Yes	○ No
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	○ Yes	○ No
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	○ Yes	○ No
• Other progesterone-only pills	○ Yes	○ No
• Combined oral contraceptive pill	○ Yes	○ No
• Other intra-uterine devices	○ Yes	○ No
• Condoms	○ Yes	○ No
• Cervical cap	○ Yes	○ No
• Sponge	○ Yes	○ No
• Withdrawal	○ Yes	○ No
• Other	○ Yes	○ No
• None	○ Yes	○ No
Indicate from the list below the reason for contraceptive failure		
• Missed oral contraception	○ Yes	○ No
• Other medication or intercurrent illness interacting with oral contraception	○ Yes	○ No
• Identified mishap with barrier method	○ Yes	○ No
• Unknown	○ Yes	○ No
• Had the patient committed to complete and continuous sexual abstinence	○ Yes	○ No
• Was the drug started despite patient already being pregnant?	○ Yes	○ No
• Did patient receive educational materials on the potential risk of teratogenicity?	○ Yes	○ No
• Did patient receive instructions on need to avoid pregnancy?	○ Yes	○ No

UK

Pregnancy reports for pomalidomide must be sent to Accord Medical information IMMEDIATELY

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Background Information on Reason for Pregnancy

Prenatal information

Date of Last Menstrual Period: D D M O N Y Y Y Y

Estimated Delivery Date: D D M O N Y Y Y Y

Pregnancy test

Urine Qualitative ◯ Reference Range: Date: D D M O N Y Y Y Y

Serum Quantitative ◯ Reference Range: Date: D D M O N Y Y Y Y

Past Obstetric History

Year of Pregnancy	Outcome				Gestational Age	Type of Delivery
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		

Birth defects

Was there any birth defect from any pregnancy?	◯ Yes	◯ No	◯ Unknown
Is there any family history of any congenital abnormality abstinence?	◯ Yes	◯ No	◯ Unknown

If yes to either of these questions, please provide details below:

Maternal Past Medical History

Condition	Dates	Treatment	Outcome
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		

UK

Pregnancy reports for pomalidomide must be sent to Accord Medical information IMMEDIATELY

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Maternal Current Medical Conditions

Condition	From	Treatment
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	

Maternal Social History

Alcohol ◯ Yes ◯ No	Tobacco ◯ Yes ◯ No	IV or recreational drug use ◯ Yes ◯ No
If yes, amount/units per day:	If yes, amount per day:	If yes, provide details:

Maternal medication during pregnancy and in 4 weeks before pregnancy

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Dates		Indication
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	

Name of person completing this form

Name:	Signature:
Date: D D M O N Y Y Y Y	

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UK

Pregnancy reports for pomalidomide must be sent to Accord Medical information IMMEDIATELY

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com

Data Privacy Notice

Your personal data will be processed by Accord-UK Ltd, as marketing authorisation holder of pharmaceutical products and its worldwide affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes.

To conduct risk management programme activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

Accord may disclose your personal information to regulatory authorities, affiliates of the Accord Group, service providers or other collaborators. Some of these entities may be located outside of the UK. Accord will take appropriate measures, such as implementing standard data protection clauses, to ensure that your personal information will be kept secure in accordance with applicable data protection law. Accord will only retain your personal data for the length of time required by law.

For further information on how Accord-UK Ltd processes your personal data along with your rights, please refer to our privacy notice located at https://www.accord-healthcare.com/

Reporter's Signature (required):

Signature :

Date signed: D D M O N Y Y Y Y

On behalf of Accord, thank you for providing information that will assist us in our commitment to patient safety.

UK

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com
NOTE: Please use the first three letters of the month (e.g.: JAN)

Reporter information

Reporter Name:	
Address:	
City, County, Country:	
Phone No.:	
Fax No.:	

Patient information

Patient ID: ____ Date of Birth: D D M O N Y Y Y Y Ethnicity: ○ White ○ African-Caribbean ○ Other, specify below: ____

Partner of patient information

○ Not applicable Ethnicity: ○ White ○ African-Caribbean ○ Other, specify below: ____

Pregnancy outcome

Date of delivery: D D M O N Y Y Y Y Gestation age at delivery: ____

Normal	○ No	○ Yes
C-section	○ No	○ Yes
Induced	○ No	○ Yes
Ectopic pregnancy	○ No	○ Yes
Elective termination	○ No	○ Yes
Spontaneous abortion (≤20 weeks)	○ No	○ Yes
Foetal death/stillbirth (>20 weeks)	○ No	○ Yes
Were the products of conception examined?	○ No	○ Yes

Date: D D M O N Y Y Y Y
Weeks from LMP: ____

If yes, was the foetus normal? ○ No ○ Yes ○ Unknown If no, describe below: ____

Obstetrics information

Complications during pregnancy	○ No	○ Yes	If yes, please specify ____
Complications during labour/delivery	○ No	○ Yes	If yes, please specify ____
Post-partum maternal complications	○ No	○ Yes	If yes, please specify ____

Foetal outcome

Live normal infant	○ No	○ Yes	
Foetal distress	○ No	○ Yes	
Intra-uterine growth retardation	○ No	○ Yes	
Neonatal complication	○ No	○ Yes	If yes, please specify ____
Birth defect noted?	○ No	○ Yes	If yes, please specify ____

Sex: ○ Male ○ Female Birth weight: ____ lbs ____ oz. or ____ kg Length: ____ inches or ____ cm.

Apgar score: 1 min: ____ 5 min: ____ 10 min: ____ ○ Unknown

Signature of person completing this form

Signature: ____ Date: D D M O N Y Y Y Y

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UK

This form must be returned to Accord: Phone: 01271 385257 Email: medinfo@accord-healthcare.com

Drug Safety Data Privacy notice

Your personal data will be processed by Accord-UK Ltd, as marketing authorisation holder of pharmaceutical products and its worldwide affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes.

To conduct risk management programme activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

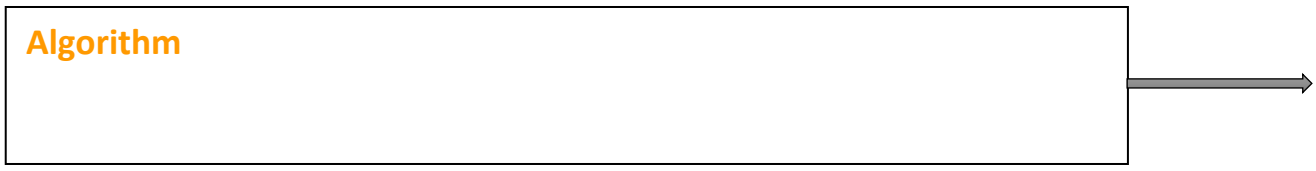
Accord may disclose your personal information to regulatory authorities, affiliates of the Accord Group, service providers or other collaborators. Some of these entities may be located outside of the UK. Accord will take appropriate measures, such as implementing standard data protection clauses, to ensure that your personal information will be kept secure in accordance with applicable data protection law. Accord will only retain your personal data for the length of time required by law.

For further information on how Accord-UK Ltd processes your personal data along with your rights, please refer to our privacy notice located at https://www.accord-healthcare.com/

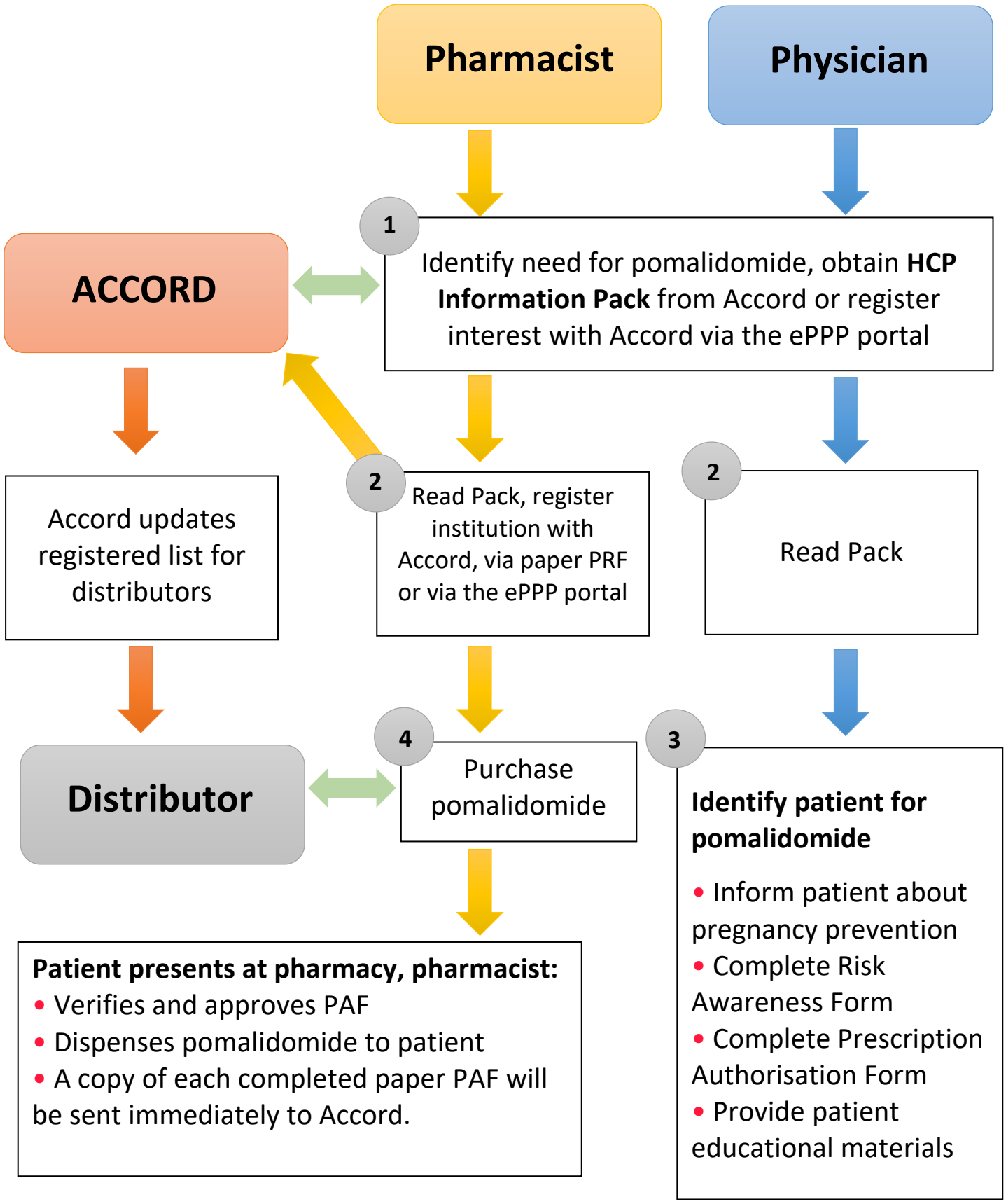
Reporter's Signature (required):

Signature:	Date signed:	D	D	M	O	N	Y	Y	Y	Y

On behalf of Accord, thank you for providing information that will assist us in our commitment to patient safety.


Algorithm

Pharmacy registration and dispensing of pomalidomide



Frequently Asked Questions

Frequently asked questions (FAQs) – UK

Where can I get further copies of the Pomalidomide Healthcare Professional's Information Pack or the patient materials?

All materials can be obtained via the ePPP Portal www.accord-eppp.co.uk or on the Accord product site: accord-healthcare-products.co.uk.

If you would like further paper copies of the pomalidomide Healthcare Professional's Information Pack or any other materials for healthcare professionals or patients, please e-mail Accord using the contact details below, or by speaking to any Accord representative.
Email: rmpteam@accord-healthcare.com

What must I do prior to ordering or dispensing pomalidomide?
All pharmacies must register with Accord prior to ordering or dispensing pomalidomide. You will need to register the dispensing pharmacy using either the ePPP portal or paper Pharmacy Registration Form. Completed paper Pharmacy Registration Forms should be sent via email (rmpteam@accord-healthcare.com) or fax to Accord (Fax: 01271 346106).

Once you have returned a completed Pharmacy Registration Form, we will inform the distributors who will place you on the registered list.

Where do I order pomalidomide?
Once registered, to order pomalidomide please contact the Accord distributor. You must have returned the completed Pharmacy Registration Form to Accord. Accord will approve your completed registration. Once approved orders can be placed with the distributor. You will need to fax or email your order to the distributors (all orders must be received in writing):
Healthnet Homecare (UK) Ltd
Units 1 & 2 Orbit Business Park, Swadlincote, DE11 0WU
Email: wholesaleorders@healthnethomecare.co.uk
Tel: 08000 833 060

How should I report an adverse event or suspected pregnancy?
Adverse events should be reported to Accord medical information. Pregnancy reporting forms and Pregnancy Outcome Forms are included in this Healthcare Professional's Information Pack. Completed forms should be forwarded to the Accord medical information using the contact details below:
Tel: 01271 385257 Email: medinfo@accord-healthcare.com

You may also report any adverse events to the MHRA via the Yellow Card scheme website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

What are the contact details for Accord Medical Information?
To contact Accord in the UK for medical information, please telephone or email the Medical Information department using the contact details below:
Tel: 01271 385257 Email: medinfo@accord-healthcare.com

How will Accord audit pharmacies registered for the pomalidomide Pregnancy Prevention Programme?
The terms of the pomalidomide Marketing Authorisation include a **mandatory** requirement for annual feedback to be collected on the effectiveness of the Pregnancy Prevention Programme, at a national level.

Accord have agreed with the Medicines and Healthcare Products Regulatory Agency (MHRA) that pharmacies can fulfil their obligations in this respect, by completing PAFs via the ePPP portal or sending copies of the completed paper PAFs to Accord once the prescription has been dispensed for auditing by the Accord team. This information will be provided, in an anonymised and aggregated format, to the MHRA.

It is therefore critical for pharmacies to ensure that all documentation associated with the Pregnancy Prevention Programme is completed accurately and that Prescription Authorisation Forms (PAFs) are provided faithfully and diligently, in the interests of patient safety.

Who do I need to contact regarding the online ePPP portal system and where do I send my Prescription Authorisation Forms?

Please contact the Accord PV team on the following contact details:
Tel: +44 (0)7917920374
Email: rmpteam@accord-healthcare.com

If you wish to use email, please scan the completed paper form and email it as an attachment or use the editable PDF file which is available on the Accord product site. PAFs can also be submitted by completing the forms on the ePPP portal.

Please keep a copy of the paper/PDF Prescription Authorisation Forms for your records.

Important Contact Information

Contact details

For information and questions on the Risk Management of Accord products, the Pregnancy Prevention Programme, pharmacy registrations or the online ePPP portal www.accord-eppp.co.uk please contact Accord PV team:
Tel: +44 (0)7917920374
Email: rmpteam@accord-healthcare.com.

For reporting of adverse events and any medical information enquiries on Accord products please contact Accord medical information team:
Tel: 01271 385257
Email: medinfo@accord-healthcare.com.

Adverse events can also be reported to the MHRA via the Yellow Card scheme website: https:/yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Distributor:
For product delivery enquires please contact –
Healthnet Homecare (UK) Ltd
Units 1 & 2 Orbit Business Park, Swadlincote, DE11 0WU
Email: wholesaleorders@healthnethomecare.co.uk
Tel: 08000 833 060