Lenalidomide

Healthcare Professional's Information Pack

UK

Version 4.0

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

For complete safety information please refer to the Summary of Product Characteristics for lenalidomide, available at the UK electronic medicines compendium (emc) website: www.medicines.org.uk

accord

Lenalidomide

Healthcare Professional's Information Pack

UK

This pack contains the information and materials needed for the prescribing and dispensing of Lenalidomide, 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 lenalidomide 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 Lenalidomide Pregnancy Prevention Programme process.

Lenalidomide is indicated:
• as monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation
• as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant
• in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy
• as monotherapy for the treatment of adult patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate
• as monotherapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma
• in combination with rituximab (anti-CD20 antibody), for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 – 3a).

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

Lenalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Lenalidomide induced, in monkeys, malformations similar to those described with thalidomide.
If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. Lenalidomide 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 4.0

MHRA approval date – 25/07/2022

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Information for Healthcare Professionals

This section contains information for healthcare professionals prescribing or dispensing lenalidomide.

Pharmacy Registration Form

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

Information for Patients

This section contains information about lenalidomide that you should give to your patients.

Treatment Initiation 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 lenalidomide to your patients.

Prescription Authorisation Forms

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

Adverse Events and Pregnancy Reporting Forms

Please report Adverse Events. This section contains forms you can use.

Treatment Checklists and Algorithm

Frequently Asked Questions

Important Contact Information

Lenalidomide
Pregnancy Prevention Programme

Information for Healthcare Professionals Prescribing or Dispensing Lenalidomide

UK

Risk Management contact details:
Tel: 01271 385 257
Fax: 01271 346106
Email: rmpteam@accord-healthcare.com

Version 2.0
MHRA approval date – 21/04/2022

This brochure contains the information needed for prescribing and dispensing lenalidomide, including information about the Pregnancy Prevention Programme (PPP). Please also refer to the summary of product Characteristics (SmPC), which can be found on the eMC website: www.medicines.org.uk for further information.

Lenalidomide Pregnancy prevention programme:
If lenalidomide 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 lenalidomide. It will provide you with information about how to follow the programme and explain your responsibilities.

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

To ensure your patients' safety, please read this brochure carefully. You must ensure that you patients fully understand what you have told them about lenalidomide and that they have provided written confirmation on the Treatment Initiation Form, before starting treatment.

Contents

1.0 Introduction

Lenalidomide is an immunomodulating medicinal product.

Two Phase III clinical studies assessed lenalidomide maintenance in patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT) was assessed in (CALGB 100104 and IFM 2005 02).

In Study CALGB 100104, patients were randomised 1:1 within 90 to 100 days after ASCT to receive either lenalidomide or placebo maintenance. The maintenance dose was 10 mg once daily on Days 1 to 28 of repeated 28- day cycles (increased up to 15 mg once daily after 3 months in the absence of dose limiting toxicity), and treatment was continued until disease progression.

The results of progression free survival (PFS) at unblinding (cut-off of 17 December 2009) showed a 62% reduction in risk of disease progression or death favouring lenalidomide over placebo. The Hazard Ratio was 0.38 (95% CI 0.27, 0.54; p <0.001). The median overall PFS was 33.9 months (95% CI not evaluable [NE], NE) in the lenalidomide arm versus 19.0 months (95% CI 16.2, 25.6) in the placebo arm. The updated PFS, using a cut-off of 01 February 2016, continued to show a PFS advantage for lenalidomide (Hazard Ratio = 0.61; p <0.001).

In Study IFM 2005-02, patients who had undergone ASCT and had achieved at least a stable disease response at the time of haematologic recovery were randomised 1:1 to receive either lenalidomide or placebo maintenance (10 mg once daily on Days 1 to 28 of repeated 28-day cycles increased up to 15 mg once daily after 3 months in the absence of dose-limiting toxicity) following 2 courses of lenalidomide consolidation (25 mg/day, Days 1 to 21 of a 28-day cycle). Treatment was to be continued until disease progression. The study was unblinded upon the recommendations of the data monitoring committee after surpassing the threshold for a preplanned interim analysis of PFS. After unblinding, patients receiving placebo were not crossed over to lenalidomide therapy prior to progressive disease. The lenalidomide arm was discontinued, as a proactive safety measure, after observing an imbalance of second primary malignancies (SPM). The results of PFS at unblinding, following a preplanned interim analysis, using a cut-off of 07 July 2010 (31.4 months follow up) showed a 48% reduction in risk of disease progression or death favouring lenalidomide over placebo. The Hazard Ratio was 0.52 (95% CI 0.41, 0.66; p <0.001). The median overall PFS was 40.1 months (95% CI 35.7, 42.4) in the lenalidomide arm versus 22.8 months (95% CI 20.7, 27.4) in the placebo arm. The updated PFS, using a cut-off of 01 February 2016 (96.7 months follow-up) continued to show a PFS advantage for lenalidomide (Hazard Ratio = 0.57; p <0.001).

A Phase III clinical study in newly diagnosed multiple myeloma (MM-020) compared lenalidomide and dexamethasone (Rd) given for 2 different durations of time (i.e. until progressive disease [Arm Rd] or for up to eighteen 28-day cycles [72 weeks, Arm Rd18]) to that of melphalan, prednisone and thalidomide (MPT) for a maximum of twelve 42-day cycles (72 weeks). The study showed a statistically significant prolongation of PFS benefit in patients receiving Rd compared to MPT. The Hazard Ratio was 0.69 (p <0.001).

Another Phase III study in newly diagnosed multiple myeloma (MM-015) was conducted to evaluate the safety and efficacy of lenalidomide in combination with melphalan and prednisone (MPR) with or without lenalidomide maintenance therapy until disease progression, to that of melphalan and prednisone for a maximum of 9 cycles.

The study showed a statistically significant prolongation of PFS benefit in patients receiving MPR+R compared to MPp+p (melphalan, prednisone, placebo + placebo maintenance). The Hazard Ratio was 0.37 ($p < 0.001$).*

In Phase III clinical studies in multiple myeloma with at least one prior therapy, the median time to progression (TTP) was 60.1 weeks in patients treated with lenalidomide/dexamethasone versus 20.1 weeks in patients treated with placebo/dexamethasone. The median PFS was 48.1 weeks in patients treated with lenalidomide/dexamethasone versus 20.0 weeks in patients treated with placebo/-dexamethasone.*

In a Phase III clinical study in myelodysplastic syndromes (MDS-004), a significant larger proportion of patients achieved the primary endpoint of transfusion independence (>182 days) on lenalidomide 10 mg compared with placebo (55.1% vs. 6.0%). The median time to transfusion independence in the lenalidomide 10 mg arm was 4.6 weeks. The median duration of transfusion independence was not reached in any of the treatment arms, but should exceed 2 years for the lenalidomide-treated subjects. The median increase in haemoglobin (Hgb) from baseline in the 10 mg arm was 6.4 g/dL.*

In a phase II study of lenalidomide (N=170) versus single agent of investigator's choice of monotherapy with either chlorambucil, cytarabine, rituximab, fludarabine, or gemcitabine (N=84) in patients with mantle cell lymphoma (MCL) who were refractory to their last regimen or had relapsed one to three times (Study MCL-002), median PFS was significantly improved for lenalidomide versus investigator's choice (37.6 versus 22.7 weeks; Hazard Ratio = 0.61, $p = 0.004$).*
*text according to SmPC

1.1 Licensed Indication

Lenalidomide is an immunomodulating medicinal product.
- Lenalidomide as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

AND
- Lenalidomide as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.

AND
- Lenalidomide in combination with dexamethasone is indicated for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.

AND

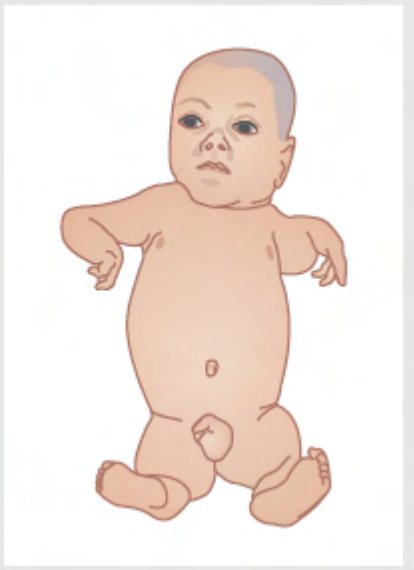
• Lenalidomide as monotherapy is indicated for the treatment of adult patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

- All patients with myelodysplastic syndrome (MDS) should be informed that a prospective Post-Authorisation Safety Study to further evaluate the safety and monitor the usage of lenalidomide in this MDS patient population will be conducted in the UK.
AND
• Lenalidomide as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
AND
• Lenalidomide in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 – 3a).

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

1.2 Lenalidomide Pregnancy Prevention Programme

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. An embryofoetal development study has been conducted in monkeys administered lenalidomide at doses up to 4mg/kg/day. Findings from this study showed that lenalidomide produced external malformations (short limbs, bent digits, wrist and/or tail, supernumerary or absent digits) in the offspring of female monkeys who received the drug during pregnancy.
Thalidomide produced similar types of malformations in the same study.



If lenalidomide is taken during pregnancy, a teratogenic effect is expected. Therefore, lenalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met.

• It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood this brochure before prescribing or dispensing lenalidomide for any patient

• The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in the attached Algorithm

• 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 Treatment Initiation Form and checklists for counselling are provided with this pack)

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

• Patients must be provided with the appropriate Patient Brochure, Treatment Initiation Form and Patient Pocket Information Card.

All of the Lenalidomide Pregnancy Prevention Programme materials are contained within the Healthcare Professional's Information Pack and additional copies can be obtained by using the contact details displayed on the front of this brochure.

You must ensure that your patient fully understands what you have told them about lenalidomide before starting the treatment.

In order to obtain lenalidomide, 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 lenalidomide for **any** patient.

• Prescribers must complete the appropriate Treatment Initiation Form with every patient before the first prescription is issued
• Pharmacies must register with Accord to be able to order and dispense lenalidomide. To do this, the pharmacist must either; contact the Accord Risk Management team using the details at the front of this brochure or use the Pharmacy Registration Form
• Every prescription for lenalidomide must be accompanied by a paper Prescription Authorisation Form, which must be completed by the prescriber and the pharmacist. A copy of each paper PAF must be sent to Accord.
• 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 lenalidomide should be limited to a maximum duration of 4 weeks according to the approved indications dosing regimens (posology) and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.
Dispensing of lenalidomide 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 lenalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription. Pharmacists are required to send copies of every Prescription Authorisation Form immediately after dispensing to Accord (Email: rmpteam@accord-healthcare.com , Fax 01271 346106).

This Healthcare Professional's Information Pack also contains Adverse Event and Pregnancy Reporting Forms, Treatment Checklists, algorithms and Treatment Initiation Forms for obtaining consent.

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of lenalidomide will only be allowed from pharmacies registered with Accord. Accord will not authorise supply of lenalidomide to pharmacies that are not registered.

The following are core requirements of the Pregnancy Prevention Programme:

• All healthcare professionals dispensing or prescribing lenalidomide must read the Lenalidomide Healthcare Professional's Information Pack

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

• Every prescription for lenalidomide must be accompanied by a Prescription Authorisation Form, which must be completed by the prescriber and the pharmacist and a copy sent to Accord.

1.3 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 lenalidomide.

For further information about the appropriate use and safety profile of lenalidomide, please refer to the SmPC, which can be found on the eMC website: www.medicines.org.uk

You must send a copy of every completed Prescription Authorisation Form immediately to Accord, for ALL patients, regardless of indication. 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 regulatory agencies, to assess the effectiveness of risk minimisation activities and will not be able to comply if pharmacies do not provide ALL their Prescription Authorisation Forms to Accord. Prescription Authorisation Forms can be sent via email, fax or post (a photocopy of the form), using the following contact details:

Risk Management (PV) Team
Accord-UK Ltd
Whiddon Valley
Barnstaple
Devon
EX32 8NS

Tel: 01271 385257
Fax: 01271 346106
Email: rmpteam@accord-healthcare.com

If you wish to use e-mail, please scan the completed form and e-mail it as an attachment or complete the editable PDF file contained on the USB in this pack.

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

2.0 Therapeutic Management Advice to Avoid Foetal Exposure

2.1 Women of Non-childbearing Potential

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 the Accord. This is a mandatory requirement. Please contact Accord (Tel: 01271 385257 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

Women of childbearing potential must never take lenalidomide if they are:
• Pregnant
• A woman who is 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 lenalidomide, foetal exposure should be avoided.
• 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 lenalidomide therapy, and even in case of dose interruption **or**
- commit to absolute and continuous abstinence, confirmed on a monthly basis.
AND
- have a medically supervised negative pregnancy test (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 sexual abstinence.

Patients should be advised to inform the prescriber prescribing her contraception about the lenalidomide treatment.

Patients should be advised to inform you if a change or stop of method of contraception is needed.

There must be no more than **3 days** between the dates of the last negative pregnancy test and the prescription. Best practice is for the pregnancy test, prescribing and dispensing to take place on the same day.

If not established on effective contraception, the patient must be referred to an appropriately trained healthcare professional for contraceptive advice in order that contraception can be initiated.

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).

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

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking lenalidomide in combination therapy, and to a lesser extent in patients with multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma taking lenalidomide monotherapy, 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 levonorgestrel-releasing intrauterine systems 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 are generally 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 lenalidomide, she must stop treatment immediately and immediately inform her prescriber.

Requirements in the event of a suspected pregnancy while on treatment with lenalidomide:
- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in teratology for evaluation and advice.
- Notify Accord immediately of all such occurrences by contacting Accord (Tel: 01271 385257 Email: rmpteam@accord-healthcare.com). Please also complete the Pregnancy Reporting Form included in this pack. Accord will wish to follow-up with you the progress of all suspected pregnancies in female patients or partners of male patient cases.
- Report the event to the Medicine and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

2.3 Men

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

Inform your patient which are the effective contraceptive methods that his female partner can use.

Lenalidomide is present in semen. Therefore, all male patients should use condoms throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential who is not using effective contraception and even if the male patient has undergone vasectomy. Patients should be instructed that if their partner does become pregnant whilst he is taking lenalidomide or within 7 days after he has stopped taking lenalidomide, 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 lenalidomide.

If the partner of a male becomes pregnant, then he must inform his prescriber immediately, then:

Refer the female partner to a physician specialised or experienced in dealing with teratology for advice and evaluation.

Notify Accord immediately by contacting Accord (Tel: 01271 385257 Email: rmpteam@accord-healthcare.com). Please also complete the Pregnancy Reporting Form included in this pack.

Accord will wish to follow-up with you the progress of all suspected pregnancies in female patients or partners of male patient cases.

Report the event to the MHRA via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

2.4 Advice to all Patients

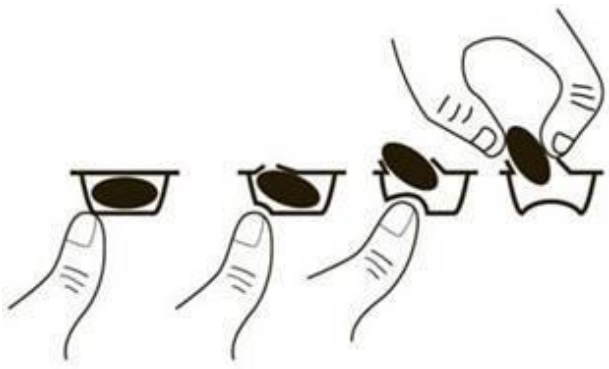
2.4.1 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

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 nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

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.

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: rmpteam@accord-healthcare.com).

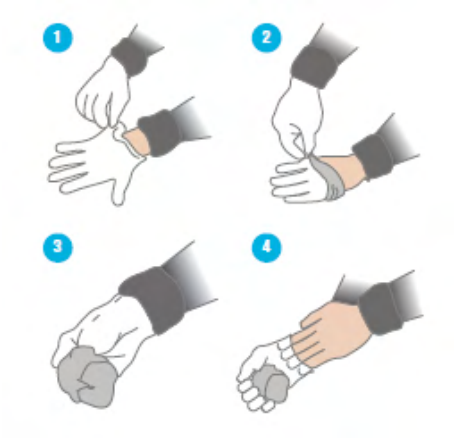
If the contents of the capsule are attached to the skin or mucous membranes

• 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.



2.4.2 Blood Donation

Patients should not donate blood during treatment and for at least 7 days after cessation of treatment with lenalidomide.

2.5 Prescribing Lenalidomide

2.5.1 Maximum Prescription Lengths

Prescriptions for women of childbearing potential can be for a maximum duration of 4 weeks according to the approved indications dosing regimens (posology). For all other patients, prescriptions of lenalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription. Lenalidomide treatment must be initiated and monitored under the supervision of physicians with expertise in managing immunomodulatory or chemotherapeutic agents and a full understanding of the risks of lenalidomide therapy and monitoring requirements.

2.5.2 Initial Prescription

Before issuing the initial prescription, you must:
• Counsel the patient on the safe use of lenalidomide in accordance with the measures described in this brochure and the SmPC, which can be found on the eMC website: www.medicines.org.uk
• Obtain their written confirmation (using the correct Treatment Initiation 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
Provide a 'Prescription Authorisation Form' to the patient with each lenalidomide prescription and this will contain:
– Patient initials, date of birth and diagnosis
– Prescriber name, signature and date
– Patient category (women of childbearing potential, women of non-childbearing potential or male)

– Confirmation that they have received counselling about the teratogenic risk of lenalidomide and the required contraceptive measures for women of childbearing potential and male patients
– For women of childbearing potential, the pregnancy test date and result
• That your patient is using effective contraception (if appropriate)

The patient must present their 'Prescription Authorisation Form' to the pharmacy along with their prescription and the pharmacy will check this form prior to dispensing lenalidomide.

2.5.3 Repeat of Subsequent Prescriptions

The patient must return to a prescriber for every repeat prescription of lenalidomide and a new PAF must be completed and submitted.

2.6 Dispensing Lenalidomide

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense lenalidomide are registered with Accord. Registration involves receiving a Healthcare Professional's Information Pack and e-mailing, faxing or posting to Accord a signed Pharmacy Registration Form to indicate agreement and compliance with the content.

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

Lenalidomide 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 Prescription Authorisation Form.

When completing paper PAF, it asks the prescriber to confirm:
• The patient's diagnosis
• Whether the patient is male or female
• If female, the patient's childbearing potential
• 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 informed consent has been completed by the patient
• That the prescriber has read and understood the contents of this Healthcare Professional's Information Pack.

When completing paper PAF, it asks the pharmacist to confirm:
• That the Prescription Authorisation Form has been completed in full by the prescriber

• 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 lenalidomide 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 lenalidomide 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 males and women of non-childbearing potential, prescriptions of lenalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription.

Pharmacists are required to send a copy of **every** Prescription Authorisation Form to **Accord** immediately after dispensing (rmpteam@accord-healthcare.com or Fax: 01271 346106).

2.6.1 Dispensing Advice

• Please ensure that you dispense lenalidomide 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 lenalidomide
• Instruct patients to return any unused lenalidomide to the pharmacy. Pharmacies must accept any unused lenalidomide returned by patients for destruction and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

3.0 Follow-up Assessment of the Effectiveness of the Programme

The terms of the Lenalidomide 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 lenalidomide.

Accord is therefore obliged to perform audits at regular intervals and to report appropriately anonymous and aggregated results to the MHRA and the European Medicines Agency (EMA).

Accord will conduct the audit from all of the completed Prescription Authorisation Forms received.

Pharmacies must send a copy of every completed paper Prescription Authorisation Form 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 Prescription Authorisation Forms are completed accurately, and that pharmacies thereby assist Accord to audit the effectiveness of the Pregnancy Prevention Programme.

4.0 Posology

4.1 Newly Diagnosed Multiple Myeloma

4.1.1 Lenalidomide Maintenance in Patients who have Undergone Autologous Stem Cell Transplantation (ASCT)

The recommended starting dose is lenalidomide 10 mg orally once daily continuously (on Days 1 to 28 of repeated 28-day cycles) given until disease progression or intolerance. After 3 cycles of lenalidomide maintenance, the dose can be increased to 15 mg orally once daily if tolerated. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.1.2 Lenalidomide in Combination with Dexamethasone Until Disease Progression in Patients who are Not Eligible for Transplant

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles.

The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of repeated 28-day cycles.

Patients may continue lenalidomide and dexamethasone therapy until disease progression or intolerance. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.1.3 Lenalidomide in Combination with Bortezomib and Dexamethasone Followed by Lenalidomide and Dexamethasone until Disease Progression in Patients who are Not Eligible for Transplant

The recommended starting dose is lenalidomide 25 mg orally once daily days 1-14 of each 21-day cycle in combination with bortezomib and dexamethasone. Bortezomib should be administered via subcutaneous injection (1.3 mg/m^2 body surface area) twice weekly on days 1, 4, 8 and 11 of each 21-day. For additional information on the dose, schedule and dose adjustments of medicinal products administered with lenalidomide, see Section 5.1 and the corresponding Summary of Product Characteristics. Up to eight 21-day treatment cycles (24 weeks of initial treatment) are recommended. Continue lenalidomide 25 mg orally once daily on days 1-21 of repeated 28-day cycles in combination with dexamethasone. Treatment should be continued until disease progression or unacceptable Toxicity. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.1.4 Lenalidomide in Combination with Melphalan and Prednisone Followed by Lenalidomide Maintenance in Patients who are Not Eligible for Transplant

The recommended starting dose is lenalidomide 10 mg orally once daily on Days 1 to 21 of repeated 28-day cycles for up to 9 cycles, melphalan 0.18 mg/kg orally on Days 1 to 4 of repeated 28-day cycles, prednisone 2 mg/kg orally on Days 1 to 4 of repeated 28-day cycles. Patients who complete 9 cycles or who are unable to complete the combination therapy due to intolerance are treated with lenalidomide monotherapy as follows: 10 mg orally once daily on Days 1 to 21 of repeated 28-day cycles given until disease progression. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.2 Multiple Myeloma with at Least One Prior Therapy

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on Days 1 to 4, 9 to 12, and 17 to 20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg once daily on Days 1 to 4 every 28 days.

Prescribers should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.3 Myelodysplastic Syndromes

The recommended starting dose of lenalidomide is 10 mg orally once daily on Days 1 to 21 of repeated 28-day cycles. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.4 Mantle Cell Lymphoma

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles. Dose reduction steps are provided in Section 4.2 of the SmPC.

4.5 Follicular lymphoma

The recommended starting dose of lenalidomide is 20 mg orally once daily on Days 1 to 21 of repeated 28-day cycles for up to 12 cycles of treatment. The recommended starting dose of rituximab is 375 mg/m2 intravenously every week in Cycle 1 (Days 1, 8, 15, and 22) and Day 1 of every 28-day cycle for Cycles 2 through 5. Dose reduction steps are provided in Section 4.2 of the SmPC.

5.0 Selected Risks of Lenalidomide

The following section contains advice to Healthcare Professionals about how to minimise some of the main risks associated with the use of lenalidomide. Please refer also to SmPC (Section 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects).

5.1 Tumour Flare Reaction in Mantle Cell Lymphoma and Follicular Lymphoma Patients

Tumour flare reaction (TFR) has commonly been observed in patients with mantle cell lymphoma who were treated with lenalidomide and very commonly observed in patients with follicular lymphoma treated with lenalidomide and rituximab. The patients at risk of TFR are those with high tumour burden prior to treatment. Caution should be practised when introducing these patients to lenalidomide. These patients should be monitored closely, especially during the first cycle or dose-escalation and appropriate precautions taken.

At the prescriber's discretion, lenalidomide may be continued in patients with Grade 1 or 2 TFR without interruption or modification. At the prescriber's discretion, therapy with non-steroidal anti-inflammatory drugs (NSAIDs), limited duration corticosteroids, and/or narcotic analgesics may be administered. In patients with Grade 3 or 4 TFR, withhold treatment with lenalidomide and initiate therapy with NSAIDs, corticosteroids and/or narcotic analgesics. When TFR resolves to ≤ Grade 1, restart lenalidomide treatment at the same dose level for the rest of the cycle. Patients may be treated for management of symptoms per the guidance for treatment of Grade 1 and 2 TFR.

5.2 Second Primary Malignancies

The risk of occurrence of Second Primary Malignancies (SPM) must be taken into account before initiating treatment with lenalidomide either in combination with melphalan or immediately following high-dose melphalan and ASCT. Prescribers should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

An increase of SPM has been observed in clinical trials in previously treated myeloma patients with lenalidomide/dexamethasone compared to controls, mainly comprising of basal cell or squamous cell skin cancers.

A 2.12-fold increase in incidence rate of solid tumour SPM has been observed in patients receiving lenalidomide (9 cycles) in combination with melphalan and prednisone (1.57 per 100 person-years) compared with melphalan in combination with prednisone (0.74 per 100 person-years).

Cases of haematological SPM such as acute myeloid leukaemia (AML) have been observed in clinical trials of newly diagnosed multiple myeloma in patients taking lenalidomide in combination with melphalan or immediately following high dose melphalan and ASCT (HDM/ASCT; see Section 4.4 of the SmPC). This increase in risk of haematological SPM was not observed in clinical trials of newly diagnosed multiple myeloma in patients taking lenalidomide in combination with dexamethasone compared to thalidomide in combination with melphalan and prednisone.

5.3 Progression to Acute Myeloid Leukaemia in Low- and Int-1 risk MDS Patients

Baseline variables including complex cytogenetics and TP53 mutation are associated with progression to AML in subjects who are transfusion dependent and have a Del (5q) abnormality. As a consequence, the benefit/risk balance of lenalidomide when MDS is associated with Del (5q) and complex cytogenetics is unknown (see Section 4.4 of the SmPC).

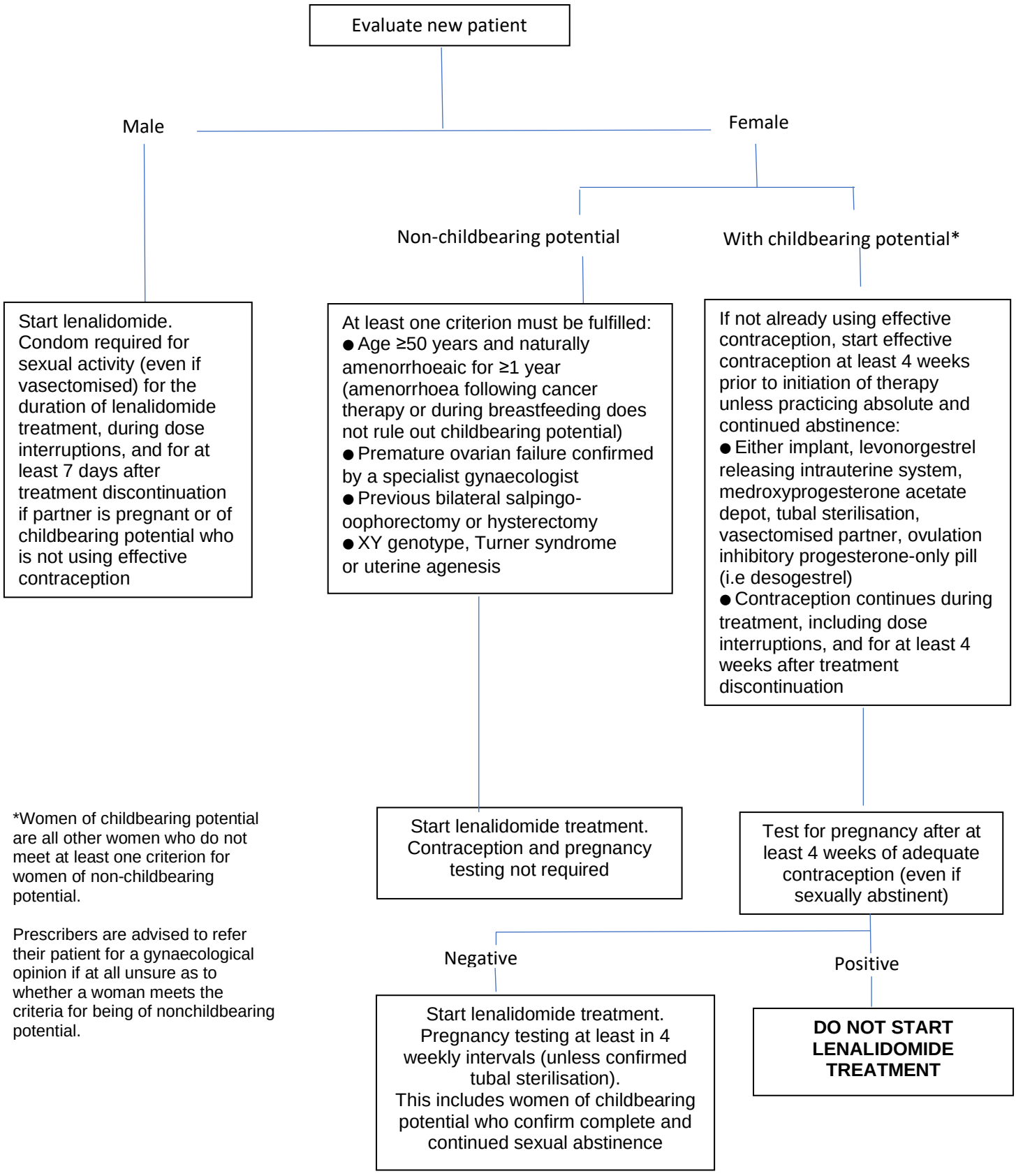
6.0 Reporting Adverse Events

The safe use of lenalidomide is of paramount importance.

Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Adverse Event Report forms and Pregnancy Reporting forms are included in this pack and should be forwarded to Accord (Tel: 01271 385257 Fax: 01271 346106; Email: rmpteam@accord-healthcare.com).

Report the event to the MHRA via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

7.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



*Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.

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 nonchildbearing potential.

8.0 Contact Details

For information and questions on the Risk Management of Accord products, the Pregnancy Prevention Programme, pharmacy registrations and reporting of adverse events please contact Accord: Tel: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com.

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

For product delivery enquires please contact the distributor –
Pharmaxo Pharmacy Services Limited, Unit A15 Fiveways Light Industrial Estate, Westwells Road, Corsham, Wiltshire, SN13 9RG
Email: wholesale@pharmaxo.com
Telephone: 01225 302188 - option 3
Fax: 01225 812777

Pharmacy Registration Form

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

Lenalidomide Accord Pharmacy Registration Form – Part 1

To be completed by the Chief Pharmacist or appointed deputy.

Institution name:	
Chief Pharmacist (or appointed deputy):	
Pharmacist GPhC / PSNI Registration Number:	
Contact telephone number:	
Email:	
Pharmacy GPhC / PSNI Registration Number (if applicable):	
Dispensing Pharmacy Address:	Delivery Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:
Ordering Address (if different to delivery address):	

By registering ..... [name of pharmacy] to order and dispense Lenalidomide Accord, I agree to implement and ensure compliance with the risk minimisation measures associated with the Pregnancy Prevention Programme (PPP) for Lenalidomide Accord and adhere to the following requirements:

1	I have read and understood the Lenalidomide Accord Healthcare Professional Brochure.	TICK
2	All pharmacists who dispense Lenalidomide Accord will have read and understood the Healthcare Professional Brochure and will ensure that the pregnancy prevention measures have been implemented before dispensing Lenalidomide Accord.	TICK
3	Prescriptions for Lenalidomide Accord will be dispensed only if accompanied by a Prescription Authorisation Form (PAF).	TICK
4	The dispensing pharmacist will check the PAF for completeness and/or request any missing information from the prescriber or patient and complete the dispensing pharmacist section of the PAF, prior to dispensing Lenalidomide Accord.	TICK
5	For a **woman of childbearing potential (WCBP)**, the dispensing pharmacist will check that the PAF confirms: a) the WCBP has been counselled/reminded about 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 Lenalidomide Accord is within 7 days of the prescription date d) the supply of treatment is no more than 4 weeks.	TICK
6	For **male patients**, the dispensing pharmacist will check that the PAF confirms: a) the patient has been counselled/reminded about teratogenic risk and the requirement to use a condom if sexually active with a pregnant woman or a woman of childbearing potential not using effective contraception. b) the supply of treatment is no more than 12 weeks	TICK
7	For **women not of childbearing potential** the dispensing pharmacist will check the supply of treatment is no more than 12 weeks	TICK
8	If supplied with Lenalidomide Accord, it will **only** be dispensed to the patient by the pharmacy registered with Accord, to fulfil the requirements of the PPP for Lenalidomide Accord. **Wholesaling is strictly prohibited.**	TICK
9	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 Lenalidomide Accord.	TICK
10	After dispensing, paper Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years. A copy of each completed paper Prescription Authorisation Form will be sent immediately to Accord.	TICK

I understand that if during the period of registration I am unable to fulfil requirements 1 - 10, the above named-pharmacy will be de-registered by Accord and I will be unable to order any further Lenalidomide Accord and required to go through the registration process again, following any necessary remedial action(s). I acknowledge this registration to order and dispense Lenalidomide Accord is valid for 2 years only, after which I am required to re-register the above-named pharmacy should I wish to continue to order and dispense Lenalidomide Accord. I understand that my personal data will be processed by Accord, for the purpose of administering the PPP for Lenalidomide Accord and that 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.

Sign:				
Print:	Date:	DD	MM	YYYY

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.

Lenalidomide Accord Pharmacy Registration Form – Part 2

If you would like to register additional pharmacy sites to be covered by your registration please provide details below.

Institution name:

Additional pharmacy sites covered by registration with Accord to supply Lenalidomide Accord

Name of Hospital/Pharmacy:

Pharmacy contact:

Pharmacy GPhC / PSNI Registration Number (if applicable):

Dispensing Pharmacy Address:	Delivery Address (if different):

Ordering Address (if different to delivery address):

Tel:	Tel:
Fax:	Fax:
Email:	Email:

Name of Hospital/Pharmacy:

Pharmacy contact:

Pharmacy GPhC / PSNI Registration Number (if applicable):

Dispensing Pharmacy Address:	Delivery Address (if different):

Ordering Address (if different to delivery address):

Tel:	Tel:
Fax:	Fax:
Email:	Email:

Name of Hospital/Pharmacy:

Pharmacy contact:

Pharmacy GPhC / PSNI Registration Number (if applicable):

Dispensing Pharmacy Address:	Delivery Address (if different):

Ordering Address (if different to delivery address):

Tel:	Tel:
Fax:	Fax:
Email:	Email:

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.

MHRA approval date - 18/02/2022
BBBB4044

Information for Patients

This section contains information about lenalidomide that you should give to your patients.

Lenalidomide
Pregnancy Prevention Programme

Information for Patients Taking Lenalidomide

UK

Risk Management contact details:
Tel: 01271 385 257
Fax: 01271 346106
Email: rmpteam@accord-healthcare.com

This brochure contains information about:

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

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

Lenalidomide passes into men's semen, and is expected to cause severe birth defects or death to an unborn baby. So, 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 lenalidomide.

This brochure will not give you information about multiple myeloma, myelodysplastic syndrome, mantle cell lymphoma or follicular lymphoma. You should ask your prescriber if you have any questions.

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

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

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

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

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

Lenalidomide works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:

- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

Lenalidomide is licensed in Europe for use in adults for:

- Newly diagnosed multiple myeloma - on its own to treat patients who have had a bone marrow transplant
- Newly diagnosed multiple myeloma - in combination with other medicines to treat patients who cannot have a bone marrow transplant
- Multiple myeloma - in combination with another medicine to treat patients who have had treatment before
- Myelodysplastic syndromes due to low- or intermediate-1-risk - used alone to treat patients when all the following apply:
    - need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anaemia')
    - have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
    - other treatments used before are not suitable or do not work well enough.
- Mantle cell lymphoma - used alone to treat patients who have previously been treated with other medicines
- Previously treated follicular lymphoma - taken together with rituximab.

Lenalidomide is structurally related to thalidomide, which is known to cause severe, life threatening birth defects. Precautions must be taken to avoid exposure to lenalidomide in an unborn baby.

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

• Understand the risks of lenalidomide treatment. Please ensure you read the Package Leaflet before you use the medication as it contains information on all the side effects that can occur with lenalidomide.

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

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

• Your prescriber will have explained to you the risks of lenalidomide treatment and specific instructions that you must follow

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

• If you are a being treated for MDS you should be included in a study, which is being conducted to collect information regarding the safety of the medicinal product and to monitor its appropriate use, prior to the start of the treatment with lenalidomide.

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

Lenalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of lenalidomide is that if taken during pregnancy, it is expected to 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 lenalidomide must never be taken by:

• Women who are pregnant
• Women who could become pregnant, even if you are not planning to become pregnant, unless they follow the Lenalidomide Pregnancy Prevention Programme

Lenalidomide and Other Possible Side Effects

Like all medicines, lenalidomide 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 lenalidomide treatment.

Reporting of Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed not listed in the Package Leaflet.

You can also report the event to the MHRA via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 **lenalidomide is expected to be harmful to an unborn child.**

• If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensure 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 interruptions and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation)

• 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 at least 4 weeks before starting treatment, throughout the duration of the treatment (including dose 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 lenalidomide. It is essential therefore, that you discuss this with your prescriber. If necessary, your hospital team can refer you to a specialist for advice on contraception

• If you suspect you are pregnant at any time whilst taking lenalidomide or in the 4 weeks after stopping, you must stop lenalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

Childbearing Potential Assessment

Female patients will be assessed by their prescriber for childbearing potential, and 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, 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.

Contraception Methods for Women of Childbearing Potential

Lenalidomide is expected to be harmful to the unborn child.
• Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans

• In order to ensure that an unborn baby is not exposed to lenalidomide, your prescriber will complete a Treatment Initiation Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 4 weeks after stopping lenalidomide

• You should never share lenalidomide 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 treatment finishes

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

• You must never take lenalidomide if:
  – You are pregnant
  – You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

If you experience any side effects whilst taking lenalidomide you should tell your prescriber or pharmacist.

Contraception Methods for Males

Lenalidomide is expected to be harmful to the unborn child

• Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans

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

• You should never share lenalidomide 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 or semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment

• Lenalidomide 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 lenalidomide even if you have had a vasectomy

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

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

If you experience any side effects whilst taking lenalidomide you should tell your prescriber or pharmacist.

Women of Non-Childbearing Potential

Lenalidomide is expected to be harmful to the unborn child.

• Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans

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

• You should never share lenalidomide 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.

If you experience any side effects whilst taking lenalidomide you should tell your prescriber or pharmacist.

Lenalidomide 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 again. Before starting treatment your prescriber will ask you to read and sign a Treatment Initiation Form, which confirms that while taking lenalidomide:

• You understand the risks of birth defects and the actions you must take to prevent this risk from occurring depending on whether you are a female patient who can become pregnant, a male patient or a female patient who cannot become pregnant

• If you are able to become pregnant you will follow the necessary requirements to prevent Pregnancy

• You understand the other important safety messages

• As a male patient, you understand the need to use condoms during treatment (including dose interruptions) and for at least 7 days after stopping lenalidomide if your partner is pregnant or is of childbearing potential and not using effective contraception.

Your prescriber will keep one copy for your medical file and provide one copy to you.

Safety Measures During Treatment

There are additional measures you must understand while taking lenalidomide.

• Please remember that your lenalidomide must only be used by you. Do not share your medicine with anyone else, even if they have similar symptoms to you

• Store your lenalidomide capsules safely, so no one else could take them by accident. Keep your lenalidomide capsules in the original box at room temperature

• Do not use after the expiry date written on the box. The expiry date refers to the last day of that month.

• Keep lenalidomide out of reach and sight of children.

Receiving Your Prescription

Your prescriber may provide you with a 'Prescription Authorisation Form' that must be provided to the pharmacist, which confirms that all of the Lenalidomide Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your lenalidomide.

For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply 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 lenalidomide suited to you

• Always take your medication exactly how your prescriber has told you. Check with your prescriber or pharmacist if you are not sure

• 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

• Lenalidomide capsules should be swallowed whole, with a glass of water

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

• Lenalidomide can be taken with or without food.

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

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

What to do if you forget to take your lenalidomide:

If you forget to take your lenalidomide and you remember within 12 hours of the missed dose you can take your lenalidomide as soon as you remember and continue with the next dose at the normal time. If it is more than 12 hours since the missed dose, leave out that dose altogether and take the next dose at the normal time.

Let your prescriber know if you have missed any doses at your next visit.

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 lenalidomide and any other medications.

End of Treatment Requirements

After completing your lenalidomide treatment, it is important that:

• You return any unused lenalidomide 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.

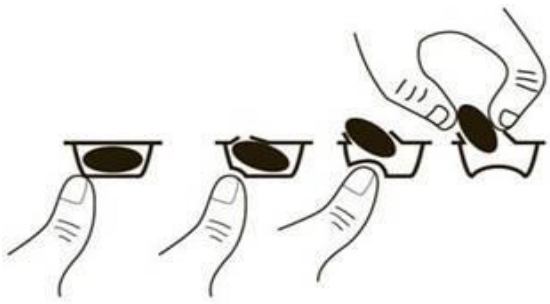
Points to Consider for Handling the Medicinal Product: for Patients, Family Members and Caregivers

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 nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

It is recommended to press only on one site at the end of the capsule (see figure below) as therefore, the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

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.

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

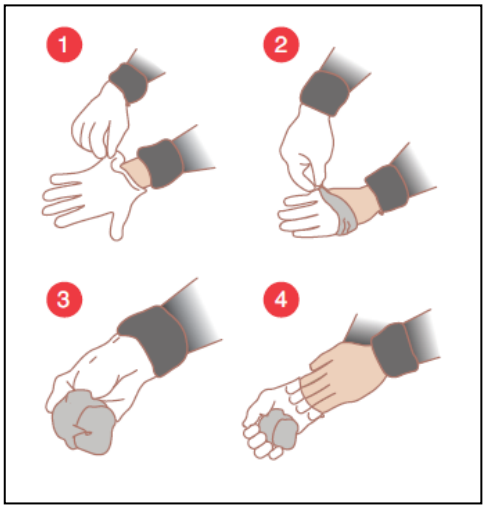
• Wash your hands thoroughly with soap and water after removing the gloves

• 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 lenalidomide treatment.

All patients

TICK	Yes, I have received and understood all the information on the risks of birth defects associated with taking lenalidomide.
TICK	Yes, I have received and understood all the information on the risks of other side effects associated with taking lenalidomide.
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 Treatment Initiation 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 lenalidomide, 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 lenalidomide.

Female patients who can become pregnant

TICK	Yes, I will use one effective method of contraception for at least 4 weeks before starting lenalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped lenalidomide 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).

Special monitoring

Because lenalidomide can cause a drop in white blood cell and platelet counts, you will have regular blood tests during treatment. Your prescriber will also monitor how well your kidneys are working. You will have blood tests more frequently in the first few months when you start treatment.

Your prescriber may adjust your dose of lenalidomide or stop your treatment based on the results of your blood tests and on your general condition. If treatment has to be stopped for any reason your prescriber will discuss other treatment options with you.

Remember, your pharmacist can give you help and advice on taking your medicines.

Emergency contact information:

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

Further information is available in the patient brochure.

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Information for Patients and Healthcare Professionals

Lenalidomide is structurally related to thalidomide and is expected to cause severe birth defects or death to an unborn baby therefore:

- Female patients of childbearing potential must always use effective contraception
- Female patients of childbearing potential must have pregnancy tests every 4 weeks, prior to each prescription, to ensure that they are not pregnant, except in the case of confirmed tubal sterilisation
- 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)
- If a female patient or female partner of a male patient suspects they are pregnant, they must contact their prescriber immediately
- You MUST tell your prescriber immediately if you experience any symptoms that causes concern.

For complete information on the side effects of lenalidomide, patients should read the Package Leaflet and HCPs should read the Summary of Product Characteristics.

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Information for Healthcare Professionals:

Prescription details

Has the patient received counselling?:	Yes/No
Childbearing potential assessment:	WCBP / WNCBP / Male
If the patient is a WCBP is she using effective contraception?	Yes/No
If the patient is male, is he using condoms, if required?	Yes/No

A completed Prescription Authorisation Form must accompany each prescription to confirm that the patient continues to use effective contraception (if required) and, in the case of a WCBP, is having a pregnancy test every 4 weeks before each prescription to ensure they are not pregnant.

inside left

Information for Healthcare Professionals:

Prescription details

This patient is receiving lenalidomide for treatment of:	
	Multiple Myeloma or
	Myelodysplastic Syndromes or
	Mantle Cell Lymphoma or
	Follicular Lymphoma

MHRA approval date 20/05/2021
BBBB2838

inside right

Treatment Initiation 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 lenalidomide to your patients.

Lenalidomide Pregnancy Prevention Programme (PPP)

Male Treatment Initiation Form

UK

Introduction

The aim of the Treatment Initiation 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 lenalidomide. 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.

This Treatment Initiation Form must be completed for each male patient prior to the initiation of their lenalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

Warning: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. 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 lenalidomide 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*

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 lenalidomide, especially the risks to women of childbearing potential. I will comply with my obligations and responsibilities as the prescribing physician of lenalidomide.

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*

Men Treatment Initiation Form

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

I understand that severe birth defects can occur with the use of lenalidomide. 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 lenalidomide.	Patient initials
I understand that lenalidomide 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 lenalidomide 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 lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Booklet and understand the contents, including the information about other possible health problems (side effects) associated with the use of lenalidomide.	Patient initials
I understand that I cannot donate blood while taking lenalidomide (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 lenalidomide, during dose interruptions and for at least 7 days after discontinuation of lenalidomide treatment.	Patient initials
I understand that I must return any unused lenalidomide 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 lenalidomide.	Patient initials

Patient Confirmation

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

Patient Signature:		Date:	DD	MM	YYYY

The personal data provided by you will be processed by Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance). For further information on how to exercise your rights and how we process your data, visit out privacy policy available on our website www.accord-healthcare.com

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 lenalidomide.

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

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK
Phone: +44(0)7917920374
Fax: 01271 346106
Website: www.accord-healthcare.co.uk

MHRA approval date - 25/07/2022
BBBB4778

Lenalidomide
Pregnancy Prevention Programme (PPP)

Women of Childbearing Potential
Treatment Initiation Form

UK

Introduction

This Treatment Initiation Form must be completed for each woman of childbearing potential prior to the initiation of their lenalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of lenalidomide. Lenalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

The aim of the Treatment Initiation 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 lenalidomide. 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: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects.
Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. 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 lenalidomide 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*

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*

Lenalidomide treatment cannot start until the patient has been established on effective method of contraception for at least 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

Woman of Childbearing Potential Treatment Initiation Form

Prescriber Confirmation

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

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 severe birth defects are expected to occur with the use of lenalidomide. 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 lenalidomide.	Patient initials
I understand that I must not take lenalidomide 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 lenalidomide.	Patient initials
I understand that before starting the lenalidomide 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 lenalidomide 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 lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Booklet and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused lenalidomide 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 information about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	Patient initials

Patient Confirmation

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

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

The personal data provided by you will be processed by Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance). For further information on how to exercise your rights and how we process your data, visit our privacy policy available on our website www.accord-healthcare.com

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 Lenalidomide.

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

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

MHRA approval date - 25/07/2022
BBBB4780

Lenalidomide
Pregnancy Prevention Programme (PPP)

Women of Non-Childbearing Potential
Treatment Initiation Form
UK

Introduction

It is mandatory that women of non-childbearing potential receive counselling and education to be made aware of the risks of lenalidomide. The aim of the Treatment Initiation 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 lenalidomide. 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.

This Treatment Initiation Form must be completed for each woman of non-childbearing potential prior to the initiation of their lenalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

Warning: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects.
Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected.
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 lenalidomide 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*

Prescriber Confirmation

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

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 severe birth defects are expected to occur with the use of lenalidomide. 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 lenalidomide.	*Patient initials*
I have read the lenalidomide Patient Booklet and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	*Patient initials*
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I know that I cannot donate blood while taking Lenalidomide (including dose interruptions) and for a least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused lenalidomide 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 lenalidomide.	*Patient initials*

Patient Confirmation

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

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

The personal data provided by you will be processed by Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance). For further information on how to exercise your rights and how we process your data, visit our privacy policy available on our website www.accord-healthcare.com

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 lenalidomide.

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

Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, UK
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Website: www.accord-healthcare.co.uk

MHRA approval date - 25/07/2022
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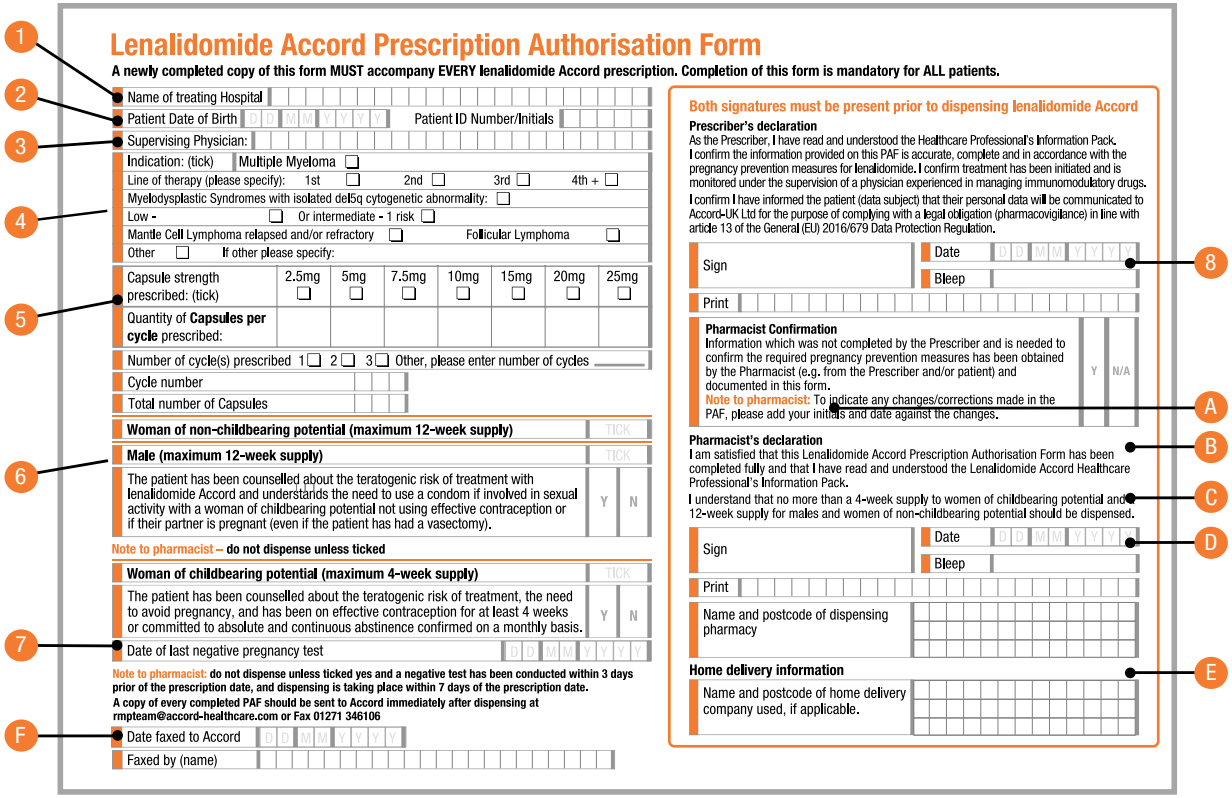
Prescription Authorisation Forms

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

A guide to Completing the Prescription Authorisation Form (PAF)

The guide will help you complete the Lenalidomide Accord Prescription Authorisation form. The form is in the Healthcare Professional's Information Pack and must be completed each time you prescribe lenalidomide Accord for all patients.

A copy of the completed forms must be returned to Accord-UK Ltd, using the contact details below.



Lenalidomide Accord Prescription Authorisation Form

A newly completed copy of this form MUST accompany EVERY lenalidomide Accord prescription. Completion of this form is mandatory for ALL patients.

1 Name of treating Hospital

2 Patient Date of Birth (D D M M Y Y Y Y) Patient ID Number/Initials

3 Supervising Physician:

Indication: (tick) Multiple Myeloma ☐

Line of therapy (please specify): 1st ☐ 2nd ☐ 3rd ☐ 4th + ☐

Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality: ☐

4 Low - ☐ Or intermediate - 1 risk ☐

Mantle Cell Lymphoma relapsed and/or refractory ☐ Follicular Lymphoma ☐

Other ☐ If other please specify:

5

Capsule strength prescribed: (tick)	2.5mg ☐	5mg ☐	7.5mg ☐	10mg ☐	15mg ☐	20mg ☐	25mg ☐
Quantity of **Capsules per cycle** prescribed:							

Number of cycle(s) prescribed 1 ☐ 2 ☐ 3 ☐ Other, please enter number of cycles

Cycle number

Total number of Capsules

6

	TICK
Woman of non-childbearing potential (maximum 12-week supply)	
Male (maximum 12-week supply)	
The patient has been counselled about the teratogenic risk of treatment with lenalidomide Accord and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).	Y / N

Note to pharmacist – **do not dispense unless ticked**

	TICK
Woman of childbearing potential (maximum 4-week supply)	
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.	Y / N

7 Date of last negative pregnancy test (D D M M Y Y Y Y)

Note to pharmacist: **do not dispense unless ticked yes and a negative test has been conducted within 3 days prior of the prescription date, and dispensing is taking place within 7 days of the prescription date.**

A copy of every completed PAF should be sent to Accord immediately after dispensing at rmpteam@accord-healthcare.com or Fax 01271 346106

F Date faxed to Accord (D D M M Y Y Y Y)

Faxed by (name)

Both signatures must be present prior to dispensing lenalidomide Accord

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 pregnancy prevention measures for lenalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

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.

Sign — Date (D D M M Y Y Y Y) — 8

Bleep

Print

Pharmacist Confirmation

Information which was not completed by the Prescriber and is needed to confirm the required pregnancy prevention measures has been obtained by the Pharmacist (e.g. from the Prescriber and/or patient) and documented in this form.

Note to pharmacist: To indicate any changes/corrections made in the PAF, please add your initials and date against the changes. — Y / N/A — A

Pharmacist's declaration

I am satisfied that this Lenalidomide Accord Prescription Authorisation Form has been completed fully and that I have read and understood the Lenalidomide Accord Healthcare Professional's Information Pack. — B

I understand that no more than a 4-week supply to women of childbearing potential and 12-week supply for males and women of non-childbearing potential should be dispensed. — C

Sign — Date (D D M M Y Y Y Y) — D

Bleep

Print

Name and postcode of dispensing pharmacy

Home delivery information — E

Name and postcode of home delivery company used, if applicable.

MHRA approval date - 25/07/2022

BBBB4777

Instructions for prescribers

1. Print the full Hospital name where the patient is treated.
2. Print the patient's Date of Birth. Do not provide confidential information (e.g. Patient Name and Hospital Number).
3. Print name clearly of supervising physician i.e physician experienced in managing immunomodulatory drugs and supervising treatment.
4. Tick the diagnosis box or state other usage – this will allow an assessment of the clinical usage of lenalidomide Accord, which is important for ongoing monitoring of the appropriateness of the Pregnancy Prevention Programme.
5. Enter the capsules strength and quantity of each strength prescribed.
6. Complete this section appropriately to indicate the counselling and appropriate use of contraception has occurred. This is a requirement of the Pregnancy Prevention Programme.
7. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescribing). If this is not the case lenalidomide Accord must not be dispensed.
8. You must sign, date and print your name to declare that all steps have been observed and that you authorise the Prescription Authorisation Form.

Instructions for pharmacists

A. Check that all relevant sections of the form have been fully completed by the prescriber
   a. Counselling and contraception measures must be in place
   b. Prescription must be accompanied by a Prescription Authorisation Form
   c. For women of childbearing potential lenalidomide Accord 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 lenalidomide Accord can be dispensed at any one time

B. Check the form does not contain confidential information (e.g. Patient Name and Hospital Number) – Accord will not accept PAFs that do not maintain anonymity.

C. Check the form is complete and legible – Accord will request that **ALL** incomplete or illegible forms are resent. If you obtained information from the prescriber or patient to complete the form, please follow the instructions in the Pharmacist Confirmation box.

D. You must sign, date and print your name to declare that the form has been completed fully and dispensing for women of childbearing potential is taking place within 7 days of the date of prescription.

E. Complete the Home delivery information if applicable.

F. Complete the "Date faxed to Accord" and "Faxed by (Name)" fields and **FAX** completed forms to Accord on **01271 346106.**

Further information and materials are available from Accord.

Telephone: +44(0)7917920374
E-mail: rmpteam@accord-healthcare.com
Fax – 01271 346106
Address: FREEPOST RRBA-EEYZ-JYUX, Accord-UK Ltd,
Medical information department, Whiddon Valley, Barnstaple, EX32 8NS

Lenalidomide Accord Prescription Authorisation Form

A newly completed copy of this form MUST accompany EVERY lenalidomide Accord prescription. Completion of this form is mandatory for ALL patients.

Name of treating Hospital

Patient Date of Birth D D M M Y Y Y Y Patient ID Number/Initials

Supervising Physician:

Indication: (tick) Multiple Myeloma ☐

Line of therapy (please specify): 1st ☐ 2nd ☐ 3rd ☐ 4th + ☐

Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality: ☐

Low - ☐ Or intermediate - 1 risk ☐

Mantle Cell Lymphoma relapsed and/or refractory ☐ Follicular Lymphoma ☐

Other ☐ If other please specify:

Capsule strength prescribed: (tick)	2.5mg ☐	5mg ☐	7.5mg ☐	10mg ☐	15mg ☐	20mg ☐	25mg ☐
Quantity of **Capsules per cycle** prescribed:							

Number of cycle(s) prescribed 1 ☐ 2 ☐ 3 ☐ Other, please enter number of cycles _____

Cycle number

Total number of Capsules

Woman of non-childbearing potential (maximum 12-week supply)	TICK

Male (maximum 12-week supply)	TICK
The patient has been counselled about the teratogenic risk of treatment with lenalidomide Accord and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).	Y / N

Note to pharmacist – do not dispense unless ticked

Woman of childbearing potential (maximum 4-week supply)	TICK
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.	Y / N
Date of last negative pregnancy test	D D M M Y Y Y Y

Note to pharmacist: do not dispense unless ticked yes and a negative test has been conducted within 3 days prior of the prescription date, and dispensing is taking place within 7 days of the prescription date.

A copy of every completed PAF should be sent to Accord immediately after dispensing at rmpteam@accord-healthcare.com or Fax 01271 346106

Date faxed to Accord D D M M Y Y Y Y

Faxed by (name)

Both signatures must be present prior to dispensing lenalidomide Accord

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 pregnancy prevention measures for lenalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

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.

Sign Date D D M M Y Y Y Y

Bleep

Print

Pharmacist Confirmation Information which was not completed by the Prescriber and is needed to confirm the required pregnancy prevention measures has been obtained by the Pharmacist (e.g. from the Prescriber and/or patient) and documented in this form. **Note to pharmacist:** To indicate any changes/corrections made in the PAF, please add your initials and date against the changes.	Y	N/A

Pharmacist's declaration

I am satisfied that this Lenalidomide Accord Prescription Authorisation Form has been completed fully and that I have read and understood the Lenalidomide Accord Healthcare Professional's Information Pack.

I understand that no more than a 4-week supply to women of childbearing potential and a 12-week supply for males and women of non-childbearing potential should be dispensed.

Sign Date D D M M Y Y Y Y

Bleep

Print

Name and postcode of dispensing pharmacy

Home delivery information

Name and postcode of home delivery company used, if applicable.

MHRA approval date - 25/07/2022
BBBB4777

Adverse Events and Pregnancy Reporting Forms

Please report Adverse Events. This section contains forms you can use.

UK

Pregnancy reports must be sent to Accord Medical information IMMEDIATELY

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@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: | Reporter's Signature:

Reporter's Phone Number:

Reporter's E-mail 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: | Physician's Signature:

Physician's Phone Number:

Physician's E-mail Address: | Physician's Fax Number:

accord

UK

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

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 sterilization (specify below)	○ Yes	○ No
○ Tubal ligation	○ Yes	○ No
○ Tubal diathermy	○ Yes	○ No
○ Tubal chips	○ Yes	○ No
• Sexual intercourse with a vasectomized 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 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

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Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@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

Expected 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		

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UK

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Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@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

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Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

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

Data Privacy Notice

Your personal data will be processed by Accord-UK Ltd, Whiddon Valley, Barnstaple, EX32 8NS, United Kingdom.
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.

Lenalidomide
Event-Specific Questionnaire for HCP - Pregnancy Outcome Form
(Patient or Partner of Patient)

UK

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

NOTE: Please use the first three letter 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-American ○ Other, specify below: ____

Partner of patient information

○ Not applicable Ethnicity: ○ White ○ African-American ○ 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

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

Drug Safety Data Privacy notice

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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.

MHRA approval date 20/05/2021
BBBB2833

Lenalidomide
Adverse Event Form

UK

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

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

○ New ○ Follow-up

Case No:

For Accord use only

Date of receipt: DD MM YYYY

Received by: (Name and organization – eg CRO, or company representative)

Source: ○ Spontaneous ○ Comp. Use ○ Lit. ○ Other, specify

For Studies Enter

Protocol/:

Site Number:

Patient Number:

Suspect Drug

Drug, Dosage-form, Strength, Route (Drug, Dosage-form, Strength, Route) (eg. Tab 5mg, oral)	Dose & frequency	Lot/ Batch no.	Therapy start date: DD/ MM / YYYY	Therapy stop date: DD/ MM / YYYY	Drug-Event Causal relationship Other, Specify (Causal relationship 1 = Not related, 2 = Related)	Indication for use of drug
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		

Action Taken

○ None ○ Unknown ○ Not Applicable
○ Dose decreased, specify ○ Permanently discontinued
○ Dose increased, specify ○ Temporarily interrupted

Patient Data

Initials: | Date of Birth: DD MM YYYY | Age:

Weight: kg | Height: cm | Gender ○ Male ○ Female

Adverse Event

Description of Adverse Event (provide diagnosis if available) - symptoms and treatment:

Event onset date: DD MM YYYY

Event stop date: DD MM YYYY

Outcome of Adverse Event

○ Recovered
○ Recovered with sequelae
○ Not recovered
○ Unknown
○ Death

Date of death: DD MM YYYY

Cause(s) of death:

Did the event result in hospitalization or prolonged hospitalization? ○ Yes ○ No

If autopsy is performed please forward report.
Please attach relevant clinical laboratory assessments to confirm the event.

accord

MHRA approval date 20/05/2021
BBBB2830

UK

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com
NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:	

Medical History

◯ Yes (if yes, please specify)
◯ None
◯ Unknown

Other Medication (Medication taken during the last 3 months prior to the event)

Drug, Dosage-form, Strength, Route (Drug, Dosage-form, Strength, Route) (eg. Tab 5mg, oral)	Dose & frequency	Therapy Start date: DD / MM / YYYY	Therapy Stop date: DD / MM / YYYY	Indication for use of drug
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Has the patient discussed this event with their healthcare professional?
◯ Yes (if yes, would you please provide their healthcare professional's contact information below)
◯ No ◯ Unknown

Healthcare professional's contact information

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Reporter

◯ Physician ◯ Nurse ◯ Pharmacist ◯ Patient ◯ Relative ◯ Other, please specify

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Pharmacy Name (if applicable)

Name:		Email:	

Signature

Sign:		Date of AE awareness:	DD	MM	YYYY

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MHRA approval date 20/05/2021
BBBB2830

UK

This form must be returned to Accord: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS, United Kingdom
Phone: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com
NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:	

Drug Safety Data Privacy notice

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This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP. Please chose one, as applicable:

- ○ I grant Accord permission to contact the prescriber/physician/HCP who treated me/the affected patient when the side effect(s) occurred and authorise him/her to provide data from my medical record related to the event(s) occurred.
- ○ No, I do not grant Accord permission to contact the prescriber/physician/HCP who treated me/the patient.

If you grant Accord permission, please provide the information of the prescriber/physician/HCP

Contact information

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Treatment Checklists and Algorithm

Combined checklist for commencing Lenalidomide treatment

This checklist is to assist you with counselling a patient before they commence lenalidomide treatment in order to assure it is used safely and correctly. Please choose the applicable column for the risk category of the patient and refer to the counselling messages provided.

Counselling	Women CBP	Women NCBP	Male
Inform of expected teratogenic risk to the unborn child	●	●	●
Inform of the need for effective contraception** for at least 4 weeks before starting treatment, throughout the entire duration of treatment, including during treatment interruptions, and for at least 4 weeks after the end of treatment, or absolute and continued abstinence	●		
Inform that even if patient has amenorrhoea, they must comply with advice on contraception	●		
Confirm patient is capable of complying with contraceptive measures	●		●
Inform of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy	●		●
Inform of the need to stop treatment immediately if female patient is suspected to be pregnant	●		
Confirm patient agrees to undergo pregnancy testing at 4 weekly intervals unless confirmed tubal sterilisation	●		
Inform of hazards and necessary precautions associated with use of Lenalidomide	●	●	●
Inform patient not to share medication	●	●	●
Inform to return unused capsules to pharmacist	●	●	●
Inform not to donate blood whilst taking Lenalidomide during treatment interruptions and for at least 7 days following discontinuation	●	●	●
Inform of the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain lenalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential not using effective contraception			●
Inform of the need not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following discontinuation			●
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	●	●	●
Inform about which are effective contraceptive methods that she or the female partner of a male patient can use	●		●
Inform that if his female partner becomes pregnant whilst he is taking lenalidomide or shortly after he has stopped taking lenalidomide, he should inform his prescriber immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice			●

MHRA approval date 20/05/2021
BBBB2834

*Refer to Healthcare Professional booklet for criteria to determine if patient is a woman of non-childbearing potential.
**Refer to Healthcare Professional booklet for information on contraception.

Contraceptive referral	Women CBP	Women NCBP	Male
Contraceptive referral required	●		
Contraceptive referral made	●		
Contraceptive consultation completed	●		

Contraception

Patient is currently established on one of the following for at least 4 weeks	Women CBP	Women NCBP	Male
Implant	●		
Levonorgestrel-releasing intrauterine system (IUS)	●		
Medroxyprogesterone acetate depot	●		
Sterilisation	●		
Sexual intercourse with a vasectomised male partner only: vasectomy must be confirmed by negative semen analysis	●		
Ovulation inhibitory progesterone-only pill (desogestrel)	●		
Patient commits to complete and absolute abstinence	●		
Negative pregnancy test before starting treatment	●		

Not of childbearing potential

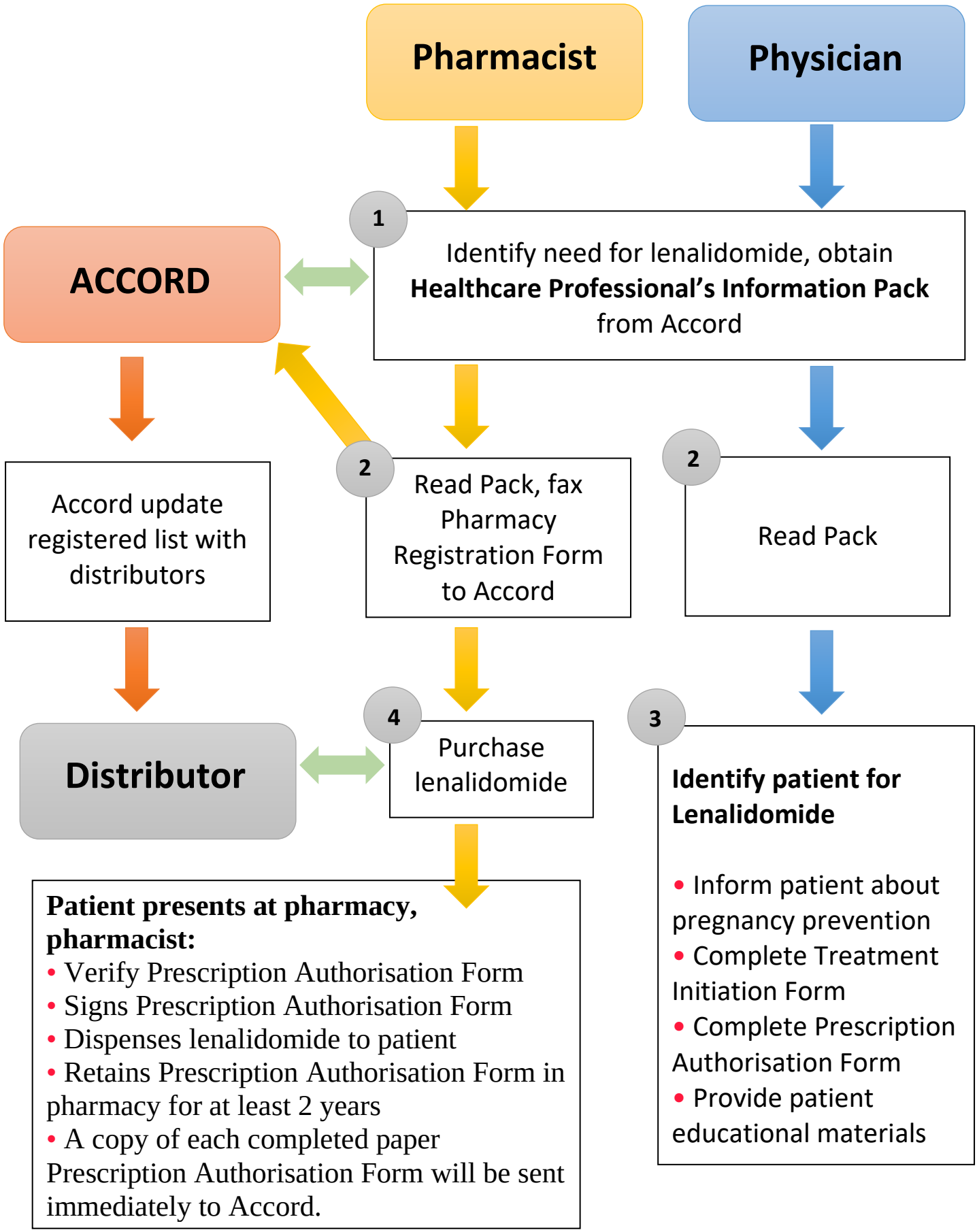
One of the following criteria have been met to determine patient is woman NCBP	Women CBP	Women NCBP	Male
Age - ≥ 50 years and naturally amenorrheic*** for ≥ 1 year not induced by chemotherapy		●	
Premature ovarian failure confirmed by specialist gynaecologist		●	
Bilateral salpingo-oophorectomy		●	
XY genotype, Turner's syndrome, uterine agenesis		●	

***Amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential

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

MHRA approval date 20/05/2021
BBBB2834

Pharmacy registration and dispensing of Lenalidomide



Frequently Asked Questions

Frequently asked questions (FAQs) – UK

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

The USB provided with the Lenalidomide Healthcare Professional's Information Pack contains electronic versions of all the important forms and may be used to print out further copies.

If you would like further copies of the Lenalidomide Healthcare Professional's Information Pack or any other materials for healthcare professionals or patients, please telephone or e-mail Accord using the contact details below, or by speaking to any Accord representative.
Tel: 01271 385257 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

What must I do prior to ordering or dispensing lenalidomide?
All pharmacies must register with Accord prior to ordering or dispensing lenalidomide. You will need to register the dispensing pharmacy using the Pharmacy Registration Form. This form is contained within this pack. Completed 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.

Do I need a registration number to order lenalidomide?
No, you just need to register with Accord by returning the Pharmacy Registration Form. We will register you and inform the distributor that you are registered and can receive lenalidomide.

Where do I order lenalidomide?
Once registered, to order lenalidomide please contact Accord distributor. You must have returned the Pharmacy Registration Form to Accord before you can place an order. You will need to fax or email your order to the distributors (all orders must be received in writing):
Pharmaxo Pharmacy Services Limited, Unit A15 Fiveways Light Industrial Estate, Westwells Road, Corsham, Wiltshire, SN13 9RG
Email: wholesale@pharmaxo.com
Telephone: 01225 302188 - option 3
Fax: 01225 812777

How should I report an adverse event?
Adverse events should be reported to Accord medical information. Adverse event reporting 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 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

You may also report any adverse events to the MHRA via the Yellow Card scheme website: www.mhra.gov.uk/yellowcard 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 Fax: 01271 346106 Email: rmpteam@accord-healthcare.com

How will Accord audit pharmacies registered for the Lenalidomide Pregnancy Prevention Programme?
The terms of the Lenalidomide 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 who complete paper Prescription Authorisation Forms (PAFs) can fulfill their obligations in this respect, by sending copies of the completed 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 and the European Medicines Agency (EMA).

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.

Important Contact Information

Contact details

For information and questions on the Risk Management of Accord products, the Pregnancy Prevention Programme, pharmacy registrations, reporting of adverse events and any medical information enquiries on Accord products please contact Accord Medical Information:
Tel: 01271 385257
Fax: 01271 346106
Email: rmpteam@accord-healthcare.com.

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

Distributor:
For product delivery enquires please contact –
Pharmaxo Pharmacy Services Limited, Unit A15 Fiveways Light Industrial Estate, Westwells Road, Corsham, Wiltshire, SN13 9RG
Email: wholesale@pharmaxo.com
Telephone: 01225 302188 - option 3
Fax: 01225 812777