Thalidomide
Pregnancy Prevention Programme

Information for Healthcare Professionals
Prescribing or Dispensing Thalidomide

UK

Risk Management contact details and Medical Information Enquiries:
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Email: rmpteam@accord-healthcare.com

This brochure is intended for healthcare professionals involved in prescribing or dispensing thalidomide, and contains information about:

•Preventing harm to unborn babies:
If thalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby.

•Thalidomide Pregnancy Prevention Programme:
This Programme is designed to prevent unborn babies being exposed to thalidomide. It will provide you with information about how to follow the programme and explain your responsibilities.

•Other side effects of thalidomide:
Ischaemic heart disease including myocardial infarction. Please refer to the Thalidomide Summary of Product Characteristics (SmPC) for full information regarding all side effects and recommended precautions. This can be found on the electronic medicines compendium (emc) website: www.medicines.org.uk.

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

It is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood this brochure.

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

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1.0 Introduction

1.1 Licensed Indication and Posology

Thalidomide belongs to a group of medicines known as 'immunomodulatory' medicines. As the prescriber or pharmacist, you play a central role in ensuring that thalidomide is used safely and in accordance with the requirements of the Pregnancy Prevention Programme.

Thalidomide is licensed for use in combination with melphalan and prednisone as first-line treatment of patients with untreated multiple myeloma, aged ≥65 years or ineligible for high dose chemotherapy. The recommended oral dose is 200 mg per day, and a maximum number of 12 cycles of 6 weeks should be used. Thalidomide should be taken as a single dose at bedtime, to reduce the impact of somnolence. Thalidomide can be taken with or without food. For full details, please refer to the Summary of Product Characteristics (SmPC), which can be found on the emc website: www.medicines.org.uk.

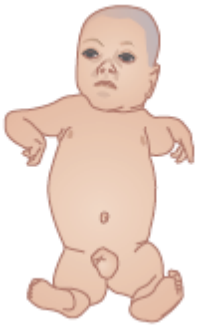
When thalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to initiation of treatment.

1.2 The Thalidomide Pregnancy Prevention Programme

Thalidomide must be prescribed and dispensed according to the Thalidomide Pregnancy Prevention Programme, because if thalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby. In the 1950s and 1960s, approximately 12,000 children were born with severe birth defects caused by thalidomide, and approximately 5,000 are alive today.

This brochure will also describe your responsibilities as a prescriber or a pharmacist and will summarise the information that you need to tell your patient to ensure they are aware of the risks and their responsibilities.

Special warnings and precautions for use:
Teratogenic effects: Thalidomide is a powerful human teratogen, inducing a high frequency of severe and life-threatening birth defects. Thalidomide must never be used by women who are pregnant or by women who could become pregnant unless all the conditions of the Thalidomide Pregnancy Prevention Programme are met. The conditions of the Thalidomide Pregnancy Prevention Programme must be fulfilled for all male and female patients.



1.3 Overview of the Healthcare Professional's Information Pack

All of the Thalidomide Pregnancy Prevention Programme materials are contained within the 'Healthcare Professional's Information Pack', and additional copies can be obtained by contacting Accord. These materials can be used for counselling patients on the risks of thalidomide and the precautions to be taken.

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

Contained in this brochure is key information for thalidomide of relevance to healthcare professionals and contains the following:

- Thalidomide Pregnancy Prevention Programme
  - educational information
  - therapy management advice to avoid foetal exposure to thalidomide
  - a distribution control system
- Safety advice of relevance to all patients
- Process for follow-up of effectiveness of the measures described in this pack
- Process for reporting adverse events in patients treated with thalidomide.

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

- Pharmacies must register with Accord using the Pharmacy Registration Form, to be able to order and dispense thalidomide
- Prescribers must complete the appropriate Treatment Initiation Form with every patient before the first prescription is issued
- Every prescription for thalidomide must be accompanied by a Prescription Authorisation Form
  – this form must be signed by both the prescriber and pharmacist, and retained for a minimum of 2 years. A copy of this form must be sent to Accord.
  – this includes instances where thalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription.
- The Pharmacy Registration Form and Prescription Authorisation Form are in subsequent sections of this pack.

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

For women of childbearing potential, prescriptions of thalidomide 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 thalidomide 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 thalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription.

This Healthcare Professional's Information Pack also contains adverse event reporting forms, treatment checklists and algorithms.

1.4 Teratogenicity: Potential or Actual Foetal Exposure to Thalidomide

Thalidomide must never be used by women who are pregnant, as just a single dose (one capsule) can induce a high frequency of severe and life-threatening birth defects. Thalidomide must never be used by women who are able to become pregnant unless they follow the Thalidomide Pregnancy Prevention Programme. Since thalidomide may be present in the seminal fluid of male patients, all male patients must also follow contraceptive measures if their partner is pregnant or is of childbearing potential and not using effective contraception.

Requirements in the event of a suspected pregnancy:

• Stop treatment immediately, if female patient

• Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation

• Notify Accord immediately by contacting the Accord medical information (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 pregnancies.

• Report the event to 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.

1.5 Safety Advice Relevant to all Patients

In addition to the teratogenic effects of thalidomide, your patients should be made aware of the risk of ischaemic heart disease, including myocardial infarction.
Please refer to the thalidomide SmPC for full information about the side effects and recommended precautions (which can be found on emc website: www.medicines.org.uk).
Your patient should be encouraged to report any unusual reactions or side effects from their medication to their prescriber. The side effects are also described in the thalidomide Package leaflet, which patients should read thoroughly.

2.0 Therapeutic Management Advice to Avoid Foetal Exposure

At treatment initiation, your female patients must be counselled on the risks of thalidomide therapy, including the risk of birth defects, other side effects and important precautions associated with thalidomide therapy.

Childbearing and Non-Childbearing Potential

In order to provide appropriate information to your female patients about the precautions they must follow when using thalidomide, it is important to determine whether your patient is or is not of childbearing potential.

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.

Women not of childbearing potential include women who fulfil at least one of the following criteria:

- Age ≥50 years and naturally amenorrhoeic 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.

2.2 Women of Childbearing Potential

A female patient is considered to have childbearing potential unless she meets at least one of the above criteria as described in section 2.1. 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 the above criteria described in section 2.1, but the prescriber considers the patient to be of non-childbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from 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.

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

Contraceptive Methods

Women of childbearing potential must use at least one effective method of contraception for at least 4 weeks before start of treatment, during treatment, and until at least 4 weeks after thalidomide treatment and even in case of dose interruptions, unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis.

If your patient is not established on effective contraception, they must be referred preferably to an appropriately trained health care professional for contraceptive advice in order that contraception can be initiated.

The following can be considered to be examples of effective methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e., desogestrel).

Because of the increased risk of venous thromboembolism in patients with multiple myeloma, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, they should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4–6 weeks after discontinuing combined oral contraception.

If your patient needs to change or stop using her method of contraception during her thalidomide therapy, she must understand the need to inform:

- The physician prescribing her contraception about the thalidomide treatment
- You, if a change or stop of method of contraception is needed.

Your patient should be advised that if she is a woman of childbearing potential and has heterosexual intercourse without using a method of contraception while taking thalidomide, or believes for any reason that she may be pregnant, she must stop treatment immediately and inform her physician immediately.

Pregnancy Testing

For women of childbearing potential, a pregnancy test must be performed prior to issuing a prescription. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

The pregnancy test must have a minimum sensitivity of 25 mIU/ml. The test must be performed by a healthcare professional, and the result must be negative before thalidomide treatment can begin or continue.

The pregnancy test must be performed during the consultation when thalidomide is being prescribed, or in the 3 days prior to the visit to the prescriber once the patient had been using effective contraception for at least 4 weeks. Further pregnancy tests must then be performed at least every 4 weeks during thalidomide treatment, and a final test conducted at least 4 weeks after treatment ends, except in the case of confirmed tubal sterilisation.

2.3 Men

Your male patients must be counselled on the risks of thalidomide therapy including the risk of birth defects, other side effects and important precautions associated with thalidomide therapy.
Patients must be informed not to donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping treatment.

Contraceptive Methods

As thalidomide is found in seminal fluid, male patients must be instructed to use a condom every time they have sexual intercourse if their partner is pregnant or is of childbearing potential and not using effective methods of contraception. Condoms must be used during treatment, during dose interruption and for at least 7 days after treatment has finished (even if he has had a vasectomy).

2.4 Advice for all Patients

Your patient must be informed not to donate blood during treatment (including during dose interruptions) and for at least 7 days after stopping treatment. If they discontinue therapy, they must return any unused thalidomide to the pharmacy.

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

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

Patients should be advised that capsules should not be opened or crushed. If powder from thalidomide makes contact with the skin, the skin should be washed immediately and thoroughly with soap and water. If thalidomide makes contact with the mucous membranes, they should be thoroughly flushed with water.

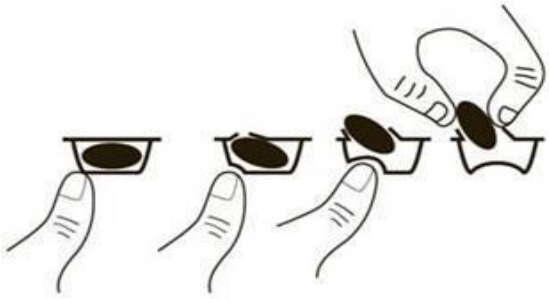
2.4.1 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

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 overleaf 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

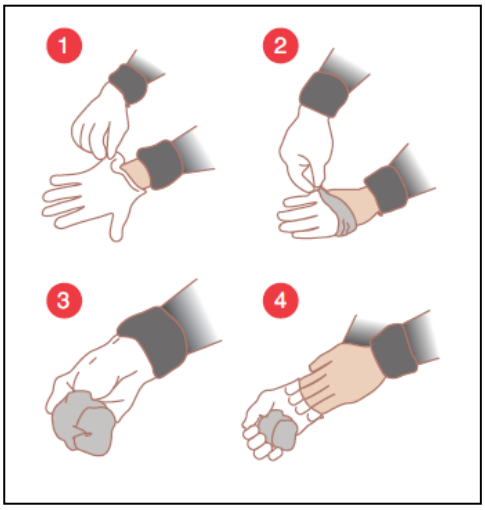
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid 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 the Accord Medical Information team (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.



3.0 Healthcare Professional's Obligations

Obligations of healthcare professionals who intend to prescribe or dispense thalidomide, are:

- The need to provide comprehensive advice and counselling to patients
- To ensure their patients are capable of complying with the requirements for the safe use of thalidomide
- To provide patients with the appropriate patient education materials
- To report any pregnancy or adverse events to Accord and the MHRA using the forms provided in the 'Healthcare Professionals Information Pack'
- To ensure that each prescription for thalidomide is accompanied by a completed Prescription Authorisation Form.

3.1 Information for Prescribers

3.1.1 Patient and Healthcare Professional Education

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

Most importantly, you will be helping to ensure that your patients understand the risks involved in taking thalidomide and that they are aware of their responsibilities in preventing foetal exposure to the drug. In addition, you may need to help your patients understand the processes involved in the Thalidomide Pregnancy Prevention Programme.

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

A summary of the Thalidomide Pregnancy Prevention Programme process can be found on the last page of this brochure.

You must ensure that your patient understands the information before they complete their section of the Treatment Initiation Form.

Please make use of the Patient Brochure and Patient Pocket Information Card to help explain the relevant information.

3.1.2 Prescribing Thalidomide

3.1.2.1 Maximum Prescription Lengths

For women of childbearing potential, prescriptions of thalidomide 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 thalidomide should occur within a maximum of 7 days of the prescription.

For all other patients, prescriptions of thalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription. Thalidomide 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 thalidomide therapy and monitoring requirements.

3.1.2.2 Initial Prescription

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of thalidomide 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
- A paper 'Prescription Authorisation Form' must be provided to the patient with each thalidomide 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 thalidomide and the required contraception measures for women of childbearing potential and male patients
  - For women of childbearing potential, the pregnancy test date and result.

The patient must present their paper 'Prescription Authorisation Form' to the pharmacy along with their prescription and the pharmacy will check this form prior to dispensing thalidomide. This Prescription Authorisation Form will contain as stated above; confirmation that they have received counselling, patient category (women of childbearing potential, women of non-childbearing potential, or male).

3.1.2.3 Repeat of Subsequent Prescriptions

The patient must return to a prescriber for every repeat prescription of thalidomide and a new PAF must be completed and submitted to Accord. You may prescribe a maximum of 4 weeks of therapy for women of childbearing potential, or 12 weeks of therapy for all other patients.

3.1.2.4 Pregnancy Testing

For women of childbearing potential, you will need to undertake a repeat pregnancy test even if the patient has not had heterosexual intercourse since the last test (except in the case of confirmed tubal sterilisation). Further information regarding pregnancy testing is provided in the pregnancy testing section.

3.2 Information for Pharmacists

As a pharmacist you play an important role in ensuring that thalidomide is used safely and correctly. Thalidomide will only be supplied to pharmacies, who have completed a 'Thalidomide Pregnancy Prevention Programme, Pharmacy Registration Form' and returned this form to Accord.

3.2.1 Dispensing Thalidomide

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense thalidomide 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 thalidomide will only be allowed from pharmacies registered with Accord Accord will not authorise purchase and supply of thalidomide to pharmacies not registered with Accord.

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 the paper PAF, it asks the prescribing physician 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 the 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.

The prescription for thalidomide must be accompanied by a PAF and this must be retained for a minimum of 2 years. A copy of this form must be sent to Accord.

For women of childbearing potential, prescriptions for thalidomide 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 thalidomide 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 thalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription.

3.2.2 Dispensing Advice

- Ensure the pack is sealed; 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 maximum 12 week supply for all other patients
- Instruct patients to return any unused thalidomide to the pharmacy.

3.2.3 Patient Education

At each supply of thalidomide, please ensure that you remind patients about the teratogenic risk and the safe use and handling of thalidomide.

4.0 Follow-up Assessment of the Effectiveness of the Programme

The terms of the Thalidomide 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 thalidomide.

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

For pharmacies completing paper PAFs, they must return all completed PAFs to Accord for auditing purposes.

5.0 The Thalidomide Pregnancy Prevention Programme at a Glance

Prescriber: You must

- Communicate the risks and benefits of thalidomide therapy to your patient
- Complete a 'Treatment Initiation Form' along with your patient (this only needs to be done once). Retain a copy with your records, and provide a copy to the patient
- Provide contraceptive counselling at treatment initiation
- Perform a pregnancy test (if appropriate) prior to every prescription
- Issue Prescription Authorisation Form to show:
    - confirmation that your patient has received counselling
    - patient category
    - pregnancy test date and result (if appropriate)
    - that your patient is using effective contraception (if appropriate)
- Remind your patient of the safe use of thalidomide at each consultation.

Pharmacist: You must

- Register with Accord in order to be supplied with thalidomide
- Remind your patient of the safe use of thalidomide, each time a prescription is dispensed
- Ensure that the Prescription Authorisation Form, which must accompany each prescription, has been fully completed
- Send a copy of the PAF to Accord once prescription dispensed.

6.0 Safety Advice Relevant to all Patients

6.1 Ischaemic Heart Disease (including myocardial infarction)

Myocardial infarction (MI) has been reported in patients receiving thalidomide, particularly in those with known risk factors. Patients with known risk factors for MI, including prior thrombosis, should be closely monitored and action should be taken to try to minimise all modifiable risk factors (e.g. smoking, hypertension, and hyperlipidaemia).

6.2 Off-label Use

Thalidomide must always be used according to the Pregnancy Prevention Programme described in this pack – these precautions must be followed, irrespective of the treatment setting, including the indication for treatment.
It is essential that the patient's diagnosis is entered on the Prescription Authorisation Form - this will allow an assessment of the clinical usage of thalidomide, which is important for ongoing monitoring of safety.

6.3 Disposal of Unwanted Medicine

Patients must be advised never to give thalidomide to another person and to return any unused capsules to their pharmacist at the end of the treatment.

6.4 Blood Donation

Patients should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.

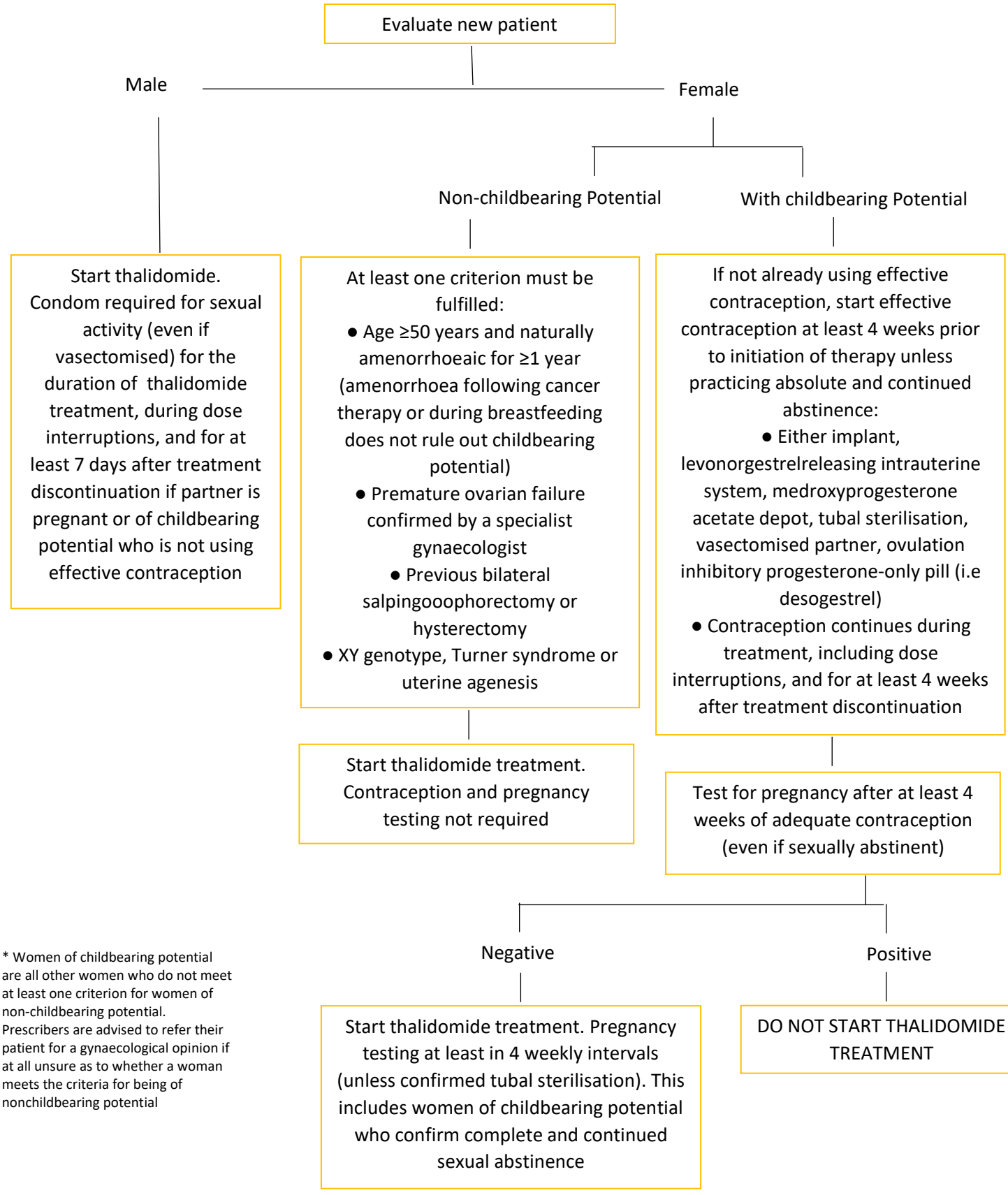
7.0 Reporting Adverse Events

The safe use of thalidomide 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 the Accord Medical information team (Tel: 01271 385257 Email: rmpteam@accord-healthcare.com).

The event should 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.

8.0 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

9.0 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 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.

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