Thalidomide BMS®
(thalidomide)

Healthcare Professional Information Guide

IRELAND

Version 7.0

Reporting of suspected adverse reactions (and cases of suspected or confirmed pregnancy or foetal exposure) after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions (and cases of suspected or confirmed pregnancy or foetal exposure) via HPRA Pharmacovigilance at www.hpra.ie. Adverse reactions (and cases of suspected or confirmed pregnancy or foetal exposure) should also be reported to Bristol-Myers Squibb (BMS) Medical Information on 1 800 749 749 or medical.information@bms.com

Risk Management contact details:
Tel: 1800 992 427
Fax: 1800 992 429
Email: rmpukire@bms.com
Medical Information Queries: medical.information@bms.com

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Contents

1.0 Introduction

This guide 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 BMS® 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:**
  This guide also contains information about ischaemic disease including myocardial infarction. Please refer to the Summary of Product Characteristics (SmPC) for full information regarding all side effects and recommended precautions. This can be found on the following website: www.medicines.ie.

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

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

For your patients' health and safety, please read this guide 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 Risk Awareness Form, before starting treatment.

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 prescribed and dispensed according to the Thalidomide BMS® Pregnancy Prevention Programme. For full details, please refer to the SmPC, which can be found on the following websites: www.medicines.ie and www.hpra.ie.

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

2.0 The Thalidomide BMS® Pregnancy Prevention Programme

Thalidomide must be prescribed and dispensed according to the Thalidomide BMS® 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 programme is designed to make sure that unborn babies are not exposed to thalidomide.

This guide will also describe your responsibilities as a prescriber or a pharmacist and provide you with 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, 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 pregnant or by women who could become pregnant unless all the conditions of the Thalidomide BMS® Pregnancy Prevention Programme are met. The conditions of the Thalidomide BMS® Pregnancy Prevention Programme must be fulfilled for all male and female patients.

2.1 Overview of 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 guide before prescribing or dispensing thalidomide for any patient.
- All men and all women of childbearing potential should undergo, at treatment initiation, counselling regarding the need to avoid foetal exposure to thalidomide during pregnancy (this must be documented via a Risk Awareness Form and checklists for counselling which are available for this purpose). You must ensure that your patient fully understands what you have told them about thalidomide before starting the treatment.
- The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in the Algorithm in Section 8.0.
- Patients should be capable of complying with the requirements of safe use of thalidomide.
- Patients must be provided with the Patient Guide, a copy of the Risk Awareness Form and Patient Pocket Information Card. These materials remind patients of the key educational information regarding the requirements of the Pregnancy Prevention Programme and some of the important risks of treatment outlined in the Healthcare Professional Information Guide.

All of the Thalidomide BMS® Pregnancy Prevention Programme materials are available electronically on the website www.hpra.ie (enter 'Thalidomide BMS' under 'Find a Medicine' and click 'EdM' under the 'Documents' column) and www.medicines.ie. Additional hard copies can be obtained from Bristol-Myers Squibb (BMS) by contacting rmpukire@bms.com.

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of Thalidomide BMS® will only be allowed from pharmacies registered with Bristol-Myers Squibb (BMS). BMS will not authorise supply of Thalidomide BMS® to pharmacies that are not registered.

The following are core requirements of the Pregnancy Prevention Programme:

- All healthcare professionals dispensing or prescribing thalidomide must read and understand the Thalidomide BMS® Healthcare Professional Information Guide.
- A controlled access programme.
- All pharmacies who dispense Thalidomide BMS® must agree to implement risk minimisation by registering with the BMS Pregnancy Prevention Programme.
- Every prescription for thalidomide must be accompanied by a Prescription Authorisation Form, which must be completed by the prescriber and the pharmacist.

3.0 Safety 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.

3.1 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 amenorrhoeic for ≥1 year*.
- Premature ovarian failure confirmed by a specialist gynaecologist.
- Previous bilateral salpingo-oophorectomy, or hysterectomy.
- XY genotype, Turner syndrome, uterine agenesis.

*Please note amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential.

Women of childbearing potential are all other women who are menstruating or perimenopausal, even those who abstain from sexual intercourse. 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.

3.2 Women of Childbearing Potential

Women of childbearing potential must never take thalidomide if they are:

- Pregnant
- Able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

In view of the expected teratogenic risk of thalidomide, foetal exposure must 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 thalidomide 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 prior to issuing a prescription (with a minimum sensitivity of 25 mIU/ml) once she has been established on contraception for at least 4 weeks, at least in 4-weekly intervals 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.

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 before initiating contraception.

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

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

Patients should be advised to inform the healthcare professional prescribing her contraception about the thalidomide treatment.

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

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, 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 to 6 weeks after discontinuing combined oral contraception.

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

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

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

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

- The prescriber prescribing her contraceptive method.
- The prescriber prescribing her thalidomide.

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

Requirements in the event of a suspected pregnancy while on treatment with Thalidomide BMS®:

- **Stop treatment immediately**.
- **Refer female patient to a physician specialised or experienced in teratology for evaluation and advice.**
- **Notify BMS immediately of all suspected pregnancies in female patients by contacting BMS Medical Information**

(Tel: 1800 749 749; Email: medical.information@bms.com). BMS will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.

- **Suspected pregnancies can also be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance website: www.hpra.ie.**

3.3 Men

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

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 should be instructed that if their partner does become pregnant whilst he is taking thalidomide or within 7 days after he has stopped taking thalidomide, 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.

Patients must be informed not to donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.

Contraceptive Methods

As thalidomide is present 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 pregnancy 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). Inform your patient about the effective contraceptive methods that his female partner can use.

If the partner of a male patient taking Thalidomide BMS® 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 BMS immediately by contacting BMS Medical Information (Tel: 1800 749 749; Email: medical.information@bms.com). BMS will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.

Suspected pregnancies can also be reported via the HPRA Pharmacovigilance website: www.hpra.ie.

3.4 Advice for all Patients

All patients should be advised not to donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with thalidomide. If they discontinue therapy, or if there are any unused capsules at the end of their treatment, they must return any unused thalidomide to the pharmacist.

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.

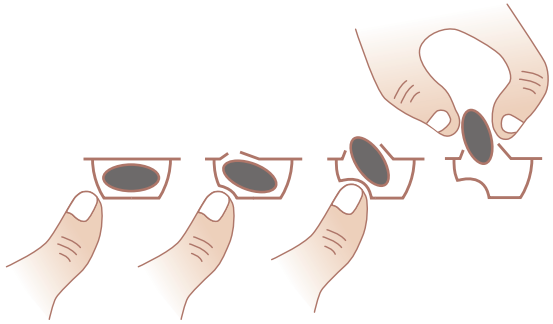
3.4.1 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

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

Keep the blisters with the capsules in the original pack.

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

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local regulations. 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 overleaf).
- Place gloves in a sealable plastic polyethylene bag and dispose them according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Patients should be advised never to give the medicinal product to another person.

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

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

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

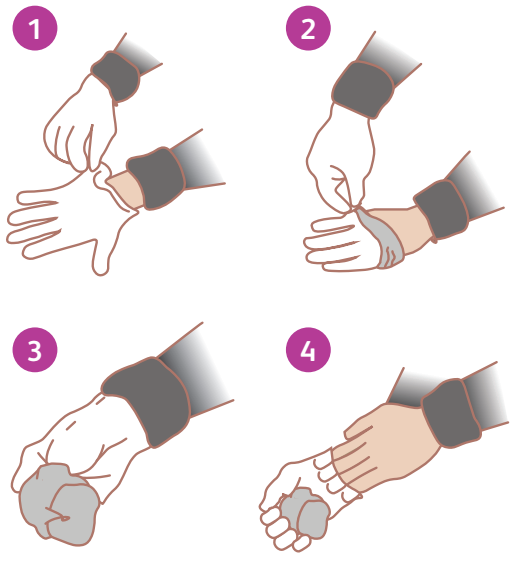
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water, then dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag. Dispose of it according to local requirements for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to BMS Medical Information (Tel: 1800 749 749 or medical.information@bms.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 your eye had contact with the powder, 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, being 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.



4.0 Prescribing and Dispensing Thalidomide BMS®

Thalidomide treatment must be initiated and monitored under the supervision of physicians with expertise in managing immunomodulatory or chemotherapeutic agents.

4.1 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 thalidomide can be for a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

4.2 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 guide and the SmPC, which can be found on the following websites: www.medicines.ie and www.hpra.ie.
- Obtain their written confirmation, using the correct Risk Awareness Form for the appropriate patient category (this only needs to be done once) that they have received and understood this information. Retain a copy with your records, and provide a copy to the patient.
- Provide contraceptive counselling and ensure that your patient is using the appropriate contraceptive measures, if relevant.
- Perform a pregnancy test (if appropriate) before initiating treatment.

Community Pharmacy Notification

A Thalidomide BMS® Community Pharmacy Dispensing Notification Form should be used to advise the community pharmacy that it has been nominated by the patient and of the need to be registered with the manufacturer in order to dispense thalidomide. The Thalidomide BMS® Community Pharmacy Dispensing Notification Form must be completed by the prescriber and faxed/emailed to the patient's nominated pharmacy on the first occasion that the patient is being prescribed thalidomide.

4.3 Subsequent Prescriptions

Before issuing subsequent prescriptions you must:

– Ensure your patient continues to understand the risks and safe use of thalidomide therapy.

– Ensure that your patient is continuing to use the appropriate contraceptive measures, if relevant.

– Perform a pregnancy test, if relevant.

– Provide a 'Prescription Authorisation Form' to the patient with each thalidomide prescription.

All prescribers must have read and understood the information contained within the Healthcare Professionals' Information Pack before prescribing Thalidomide BMS®.

4.4 Prescription Authorisation Form

Every prescription for thalidomide must be accompanied by a completed Prescription Authorisation Form.

The prescriber must confirm on the Prescription Authorisation Form:

- Patient initials, date of birth and indication.
- Name of treating hospital, prescriber name, supervising physician name, signature and date.
- Whether the patient is male, woman of childbearing potential or woman of non-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.
- That they have provided counselling on the teratogenic risk of thalidomide and the required contraceptive measures for women of childbearing potential and male patients.
- That the Risk Awareness Form has been completed and signed by the patient.
- That the prescriber has read and understands the contents of the Healthcare Professionals' Information Pack.
- The information provided on this PAF is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme for thalidomide.
- Treatment has been initiated and is monitored under the supervision of a physician with expertise in managing immunomodulatory or chemotherapeutic agents.

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 thalidomide.

The patient must return to their prescriber for every repeat prescription of thalidomide.

When completing with the Prescription Authorisation Form, it asks the pharmacist to confirm:

- That the pharmacist has read and understood the contents of the Healthcare Professionals' Information Pack.
- That the Prescription Authorisation Form has been completed in full by the prescriber.
- That dispensing for women of childbearing potential is taking place **7 days or less** from the date of prescribing.
- That the pharmacist is dispensing no more than a 4-week supply to women of childbearing potential and 12 weeks for males and women on non-childbearing potential.

If any information is missing, contact the prescriber for verification prior to dispensing.

The prescription for thalidomide must be accompanied by a PAF and this must be retained for a minimum of 2 years.

4.5 Dispensing Thalidomide BMS®

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense Thalidomide BMS® are registered with BMS. Registration involves receiving and understanding the Healthcare Professionals' Information Pack, completing and signing the Pharmacy Registration Form, and emailing or faxing the completed form to indicate agreement and compliance with the content. The Pharmacy Registration will remain valid for 2 years, after which it must be renewed to continue dispensing Thalidomide BMS®.

In order to be registered, the Chief/Superintendent Pharmacist or appointed deputy of the institution wishing to dispense must agree to implement and audit the use of the Prescription Authorisation Form.

Dispensing of Thalidomide BMS® will only be allowed from pharmacies registered with BMS. BMS will not authorise purchase and supply of Thalidomide BMS® to pharmacies not registered with BMS.

Thalidomide BMS® is supplied to pharmacies registered with BMS's Pregnancy Prevention Programme (PPP) only for the purpose of dispensing the product by the PPP registered pharmacy to the patient.

The pharmacist will need to ensure that the Prescription Authorisation Form, which must accompany each prescription, has been fully completed. The pharmacist will need to retain the Prescription Authorisation Form for at least 2 years to facilitate in the completion of the **mandatory** annual self-audit of the Prescription Authorisation Forms.

Community pharmacy notification and registration

A Thalidomide BMS® Community Pharmacy Dispensing Notification Form should be received from the prescriber/hospital pharmacy to advise the community pharmacy that it has been nominated by the patient and that it will soon be receiving a prescription for thalidomide for your patient. The pharmacy will need to register with the Thalidomide BMS® Pregnancy Prevention Programme prior to being able to order thalidomide for your patient and to dispense. If the nominated pharmacy is not already authorised to supply Thalidomide BMS®, it must first contact BMS to register with them using the Thalidomide BMS® Pharmacy Registration Form. BMS will then send the pharmacy the relevant documentation if not already received.

Ordering Thalidomide BMS®

The pharmacy must be registered with BMS to order Thalidomide BMS® and must also use a specific Thalidomide BMS® Order Form (available on request from BMS and electronically for download on the HPRA website (www.hpra.ie) or on www.medicines.ie). The pharmacy must write the name of the prescriber on the Order Form when placing an order for Thalidomide BMS®.

4.6 Dispensing Advice

For women of childbearing potential

- The date of the last negative pregnancy test, must be within the 3 days prior to the date of the prescription.
- Dispensing of thalidomide should occur within a maximum of 7 days of the prescription.
- Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.
- Prescriptions for thalidomide can be for a maximum duration of 4 weeks of treatment and continuation of treatment requires a new 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.

For all patients

- Please ensure that you dispense thalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles.
- Instruct patients to return any unused thalidomide to the pharmacy. Pharmacies must accept any unused thalidomide returned by patients for destruction, and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

Please ensure that all pharmacists within your pharmacy are educated about and familiar with the requirements of the PPP and the dispensing procedures for thalidomide.

5.0 Follow-up Assessment of the Effectiveness of the Programme and Monitoring of Off-Label Use

The terms of the Thalidomide BMS® Marketing Authorisation requires BMS 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 as well as to monitor off-label use.

BMS has agreed with the HPRA that pharmacies can fulfil their obligations in this respect, by conducting a manual self audit of the Prescription Authorisation Forms, against which the pharmacy has dispensed Thalidomide BMS® and reporting the results to BMS. This information will be provided in an anonymised and aggregated format to the HPRA. BMS will supply pharmacies with an audit pack, such that annual self auditing of pharmacies and feedback of the audit results to BMS can occur.

It is therefore critical for pharmacies to ensure that all documentation associated with the Pregnancy Prevention Programme is completed accurately and that audit results are provided faithfully and diligently, in the interest of patient safety.

6.0 Other Selected Risks of thalidomide

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 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.

6.3 Blood Donation

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

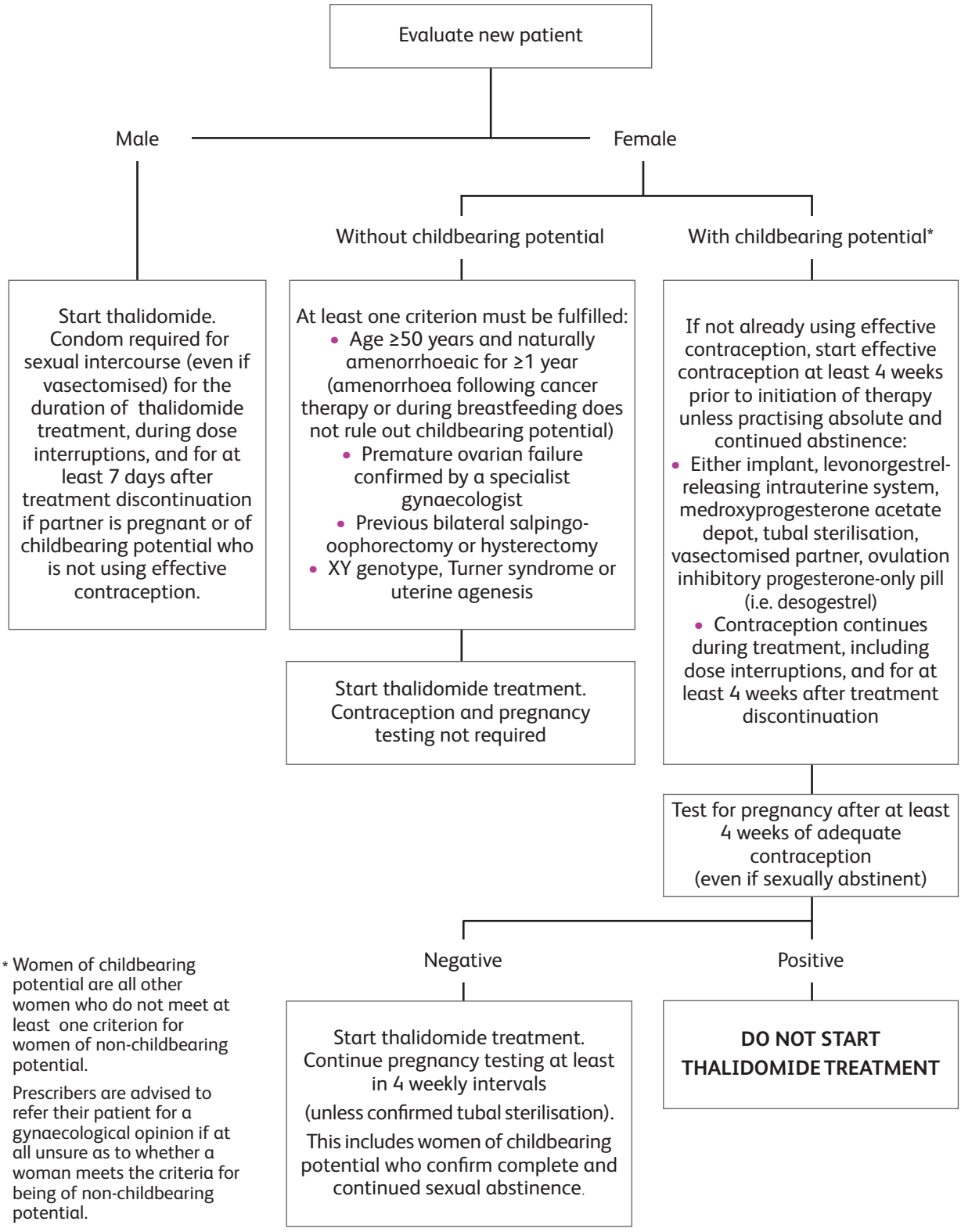
7.0 Reporting Adverse Events, Suspected and Confirmed Pregnancies, and Foetal Exposure

The safe use of thalidomide is of paramount importance.

Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported to BMS Medical Information (Tel: 1800 749 749; Email: medical.information@bms.com).

Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) can also be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance website: www.hpra.ie.

8.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm

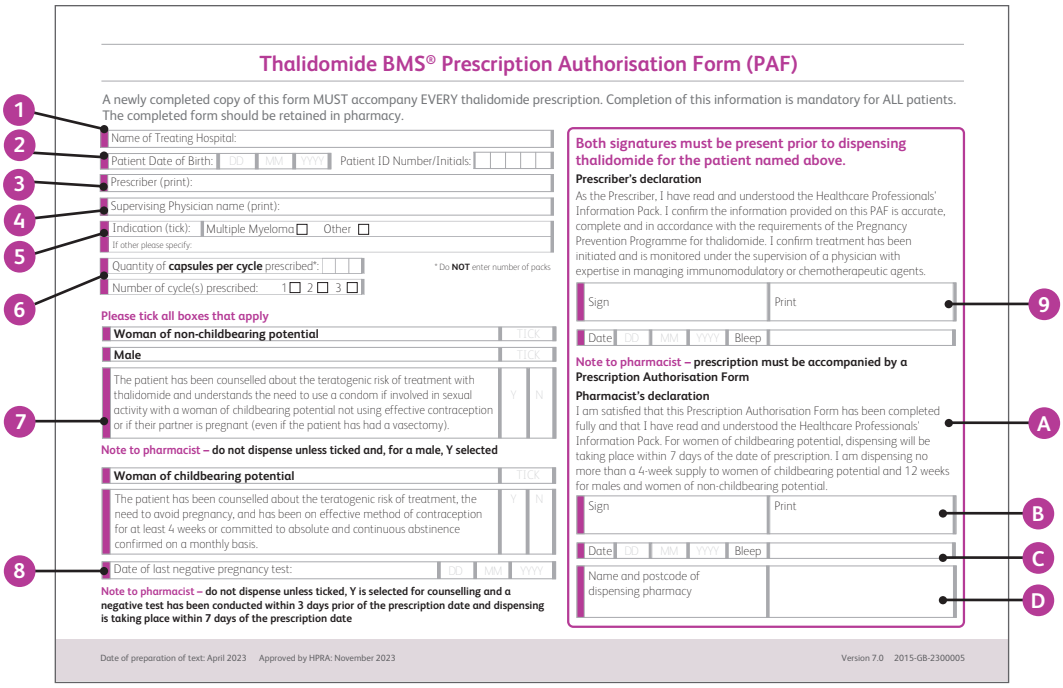


* Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.

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 non-childbearing potential.

9.0 How to Complete the Prescription Authorisation Form

This guide will help you to complete the thalidomide Prescription Authorisation Form. The form is used within the Pregnancy Prevention Programme and must be completed each time you prescribe thalidomide for all patients.



Thalidomide BMS® Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY thalidomide prescription. Completion of this information is mandatory for ALL patients. The completed form should be retained in pharmacy.

1 Name of Treating Hospital:

2 Patient Date of Birth: DD MM YYYY Patient ID Number/Initials:

3 Prescriber (print):

4 Supervising Physician name (print):

5 Indication (tick): Multiple Myeloma ☐ Other ☐
If other please specify:

6 Quantity of **capsules per cycle** prescribed*: * Do **NOT** enter number of packs
Number of cycle(s) prescribed: 1 ☐ 2 ☐ 3 ☐

Please tick all boxes that apply

	TICK	Y	N
Woman of non-childbearing potential			
Male			
The patient has been counselled about the teratogenic risk of treatment with thalidomide 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).			

7 **Note to pharmacist – do not dispense unless ticked and, for a male, Y selected**

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

8 Date of last negative pregnancy test: DD MM YYYY

Note to pharmacist – do not dispense unless ticked, Y is selected for counselling 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

Both signatures must be present prior to dispensing thalidomide for the patient named above.

Prescriber's declaration

As the Prescriber, I have read and understood the Healthcare Professionals' Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme for thalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician with expertise in managing immunomodulatory or chemotherapeutic agents.

9 Sign Print

Date DD MM YYYY Bleep

Note to pharmacist – prescription must be accompanied by a Prescription Authorisation Form

Pharmacist's declaration

I am satisfied that this Prescription Authorisation Form has been completed fully and that I have read and understood the Healthcare Professionals' Information Pack. For women of childbearing potential, dispensing will be taking place within 7 days of the date of prescription. I am dispensing no more than a 4-week supply to women of childbearing potential and 12 weeks for males and women of non-childbearing potential.

A Sign Print

B Date DD MM YYYY Bleep

C Name and postcode of dispensing pharmacy

D

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Instructions for prescribers

1. Print the full Hospital name where the patient is treated.
2. Print the patient's date of birth and initials. If the middle initial is not known please use an underscore (e.g. J_S for John Smith). Do not provide confidential information (e.g. Patient Name and Hospital Number).
3. Clearly print your name.
4. Clearly print the name of the Supervising Physician (if you are not the Supervising Physician). i.e. the physician experienced in managing immunomodulatory drugs and supervising treatment.
5. Tick the indication box or state other usage – this is for the purposes of monitoring off-label use.
6. Enter the quantity of capsules prescribed and number of cycles prescribed.
7. Complete this section appropriately to indicate that counselling and appropriate contraceptive measures are in place. This is a requirement of the Pregnancy Prevention Programme.
8. 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 thalidomide must not be dispensed.
9. 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 including:
   a. That counselling and contraceptive measures have been confirmed by the prescriber as appropriate
   b. That for woman of childbearing potential a negative pregnancy test date is provided within 3 days of the prescription date
   c. The indication, capsule strength, capsule quantity and number of cycles have been provided.

B. Check the form does not contain confidential information (e.g. Patient Name and Hospital Number).

C. Check the form is complete and legible.

D. You must sign, date and print your name to declare that the form has been completed fully and dispensing is taking place within 7 days of the date of prescription for women of childbearing potential.
   i. Dispense only a maximum of 4 weeks supply for women of childbearing potential at any one time
   ii. Dispense only a maximum of 12 weeks supply for Males and Women of Non-childbearing Potential

Further information and materials are available from BMS.
Tel: 1800 992 427
Email: rmpukire@bms.com

10.0 Prescriber's Guide to Prescribing Thalidomide BMS®

In order to initiate therapy with thalidomide:

1. Read the Thalidomide BMS® Healthcare Professionals' Information Pack.
2. Evaluate childbearing potential of patient and implement the pregnancy prevention programme as required.
3. Evaluate risks relevant to all patients, take relevant precautions and provide counselling as appropriate.
   a. Provide educational materials (Patient Guide and a Patient Pocket Information Card) to the patient.
   b. Complete Risk Awareness Form and obtain patient's signature. Retain the form and provide a photocopy to the patient.

Thalidomide treatment must be initiated and monitored under the supervision of physicians with expertise in managing immunomodulatory or chemotherapeutic agents.

For the FIRST prescription of thalidomide

Follow steps 1 to 4

1. Prescribers wishing to prescribe must read and understand the Healthcare Professionals' Information Pack.
2. Please complete a **'Community Pharmacy Dispensing Notification Form'** to notify the nominated community pharmacy that their patient will be presenting with a prescription for thalidomide. Fax or email this form to the Nominated Community Pharmacy.
3. Prescribe thalidomide using a High Technology Medicines prescription. Only a maximum of 4 weeks can be dispensed per prescription for a woman of childbearing potential. Up to a maximum of 12 weeks can be dispensed per prescription for a woman not of childbearing potential and male patients.
4. All prescriptions for thalidomide must be accompanied by a **'Thalidomide BMS® Prescription Authorisation Form'.**

For SUBSEQUENT prescriptions of thalidomide

Follow steps 1 to 3

1. All Prescribers wishing to prescribe must read and understand the Healthcare Professionals' Information Pack.
2. Prescribe thalidomide using a High Technology Medicines prescription. Only a maximum of 4 weeks can be dispensed per prescription for a woman of childbearing potential. Up to a maximum of 12 weeks can be dispensed per prescription for a woman not of childbearing potential and male patients.
3. All prescriptions for thalidomide must be accompanied by a **'Thalidomide BMS® Prescription Authorisation Form'.**

11.0 Pharmacist's guide to dispensing Thalidomide BMS®

In order to dispense thalidomide:

As a nominated community pharmacy, you will receive a **'Community Pharmacy Dispensing Notification Form'** from the Hospital or Clinic informing you that a patient will soon be presenting with a High Technology Prescription for thalidomide.

You are a Pharmacy that has NOT previously registered with Bristol-Myers Squibb (BMS)

1. Contact BMS Risk Management on 1800 992 427 to obtain the Healthcare Professionals' Information Pack, which includes all relevant information and pharmacy registration forms.
2. Read the Healthcare Professionals' Information Pack.
3. Complete the **'Pharmacy Registration Form'** and fax to BMS on 1800 992 429. You will be notified when you have been registered.
4. Once you are informed that you are registered with BMS, complete a **'Thalidomide BMS® Order Form'**.
5. Fax or email the **'Thalidomide BMS® Order Form'** to UDD at SpecialOrders@united-drug.com or on 01 463 2404. UDD aim to deliver complete orders placed before 13:30 Monday - Friday for the following working day.

You are a Pharmacy that has previously registered with BMS

1. Complete a **'Thalidomide BMS® Order Form'**.
2. Email or fax the **'Thalidomide BMS® Order Form'** to UDD at SpecialOrders@united-drug.com or on 01 463 2404. UDD aim to deliver complete orders placed before 13:30 Monday - Friday for the following working day.

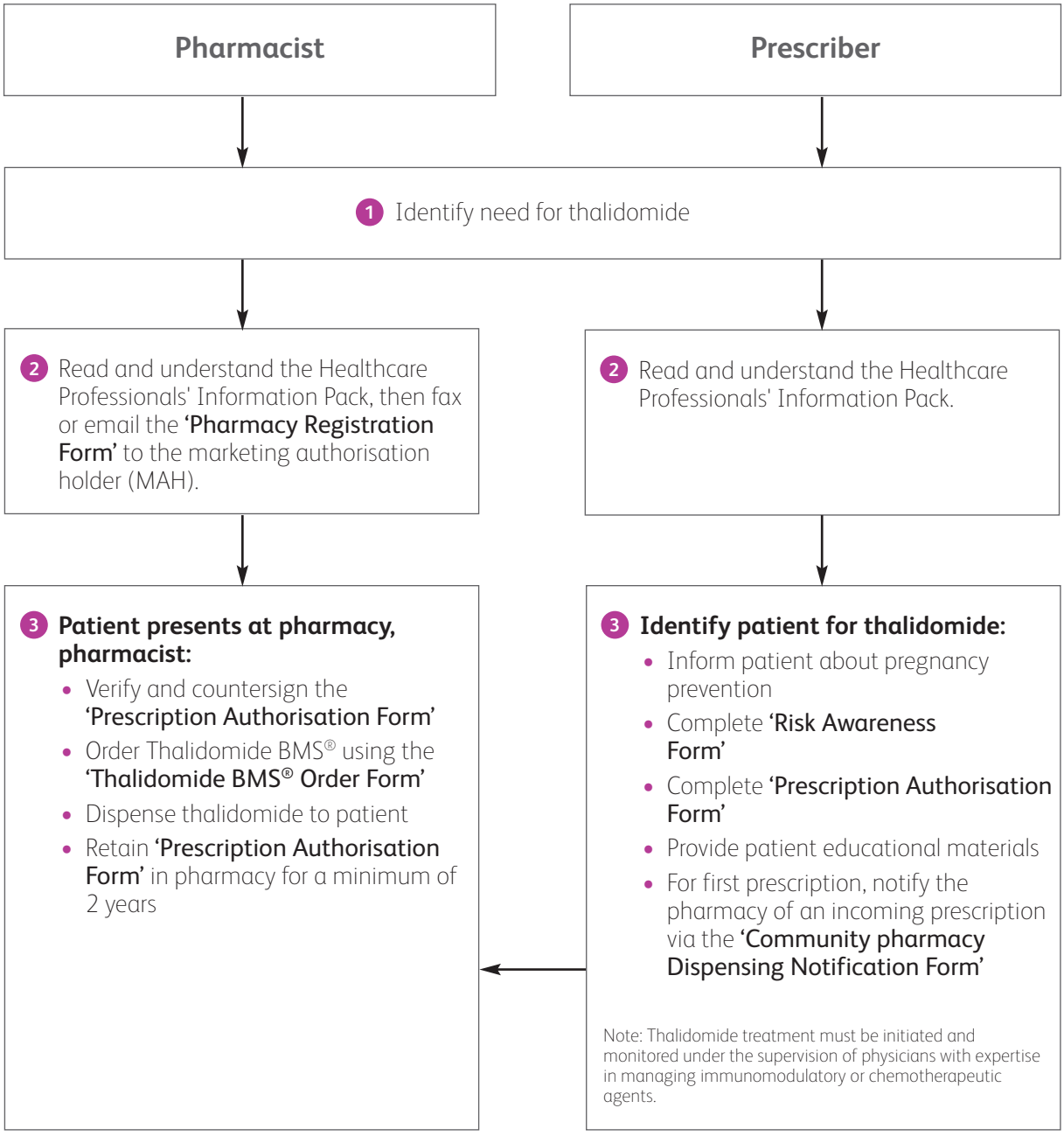
NB. Please ensure that all details are completed on this order form in full to ensure your order is processed appropriately and in a timely manner.

Complete the Pharmacist's declaration section of the **'Prescription Authorisation Form'**.

This form is retained with the High Technology Prescription in the pharmacy.

Dispense thalidomide from High Technology Prescription.

12.0 Prescribing and Dispensing of thalidomide Schematic



Pharmacies must undertake the **mandatory** annual self-audit of the Prescription Authorisation Forms.

13.0 Frequently Asked Questions (FAQs)

Where can I get further copies of the Thalidomide BMS® (thalidomide) Healthcare Professionals' Information Pack?

If you would like further copies of the Thalidomide BMS® Healthcare Professionals' Information Pack or any other materials for healthcare professionals or patients, please telephone or email Bristol-Myers Squibb (BMS) using the contact details below.

Tel: 1800 992 427
Fax: 1800 992 429
Email: rmpukire@bms.com

Electronic copies of the Healthcare Professionals' Information Pack can also be found online on the following websites: www.medicines.ie and www.hpra.ie.

For each patient category, what is the maximum supply of thalidomide available each time the patient visits the pharmacy?

The maximum supply of thalidomide for a woman of childbearing potential is 4 weeks. The maximum supply of thalidomide for a male patient and a woman of non-childbearing potential is 12 weeks.

What must I do prior to prescribing thalidomide?

All prescribers must read and understand the Thalidomide BMS® Healthcare Professionals' Information Pack and the Summary of Product Characteristics.

What must I do prior to ordering or dispensing thalidomide?

All pharmacies must register with BMS prior to ordering or dispensing thalidomide. You will need to register the dispensing pharmacy using the Pharmacy Registration Form. This form is contained within the Healthcare Professionals' Information Pack. Completed Pharmacy Registration Forms should be sent via email (rmpukire@bms.com) or fax to BMS (Fax: 1800 992 429). Once you have returned a completed Pharmacy Registration Form, the pharmacy will be placed on the registered list and we will inform the distributor.

Do I need a registration number to order thalidomide?

No, you just need to register with BMS by returning the Pharmacy Registration Form. We will register you and inform the distributor that you are registered and can receive thalidomide.

Where do I order thalidomide?

Once registered, to order thalidomide please contact our distributor – United Drug Distribution. You must have returned the Pharmacy Registration Form to BMS before you can place an order. Complete the Thalidomide BMS® Order Form contained within the Healthcare Professionals' Information Pack and fax or email your order to the distributor (all orders must be received in writing)

Distributor:
United Drug Distribution (UDD)
United Drug House
Magna Business Park
Citywest Road
Dublin 24

Tel: 01 463 2478
Fax: 01 463 2404
Email: SpecialOrders@united-drug.com

Orders placed Mondays – Fridays before 13:30 will generally be delivered the following working day.

How should I report an Adverse Event or a Suspected Pregnancy?

Adverse events and suspected pregnancy should be reported to BMS Medical Information using the contact details below:

Tel: 1800 749 749
Email: medical.information@bms.com

Suspected adverse reactions and pregnancies can be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance website: www.hpra.ie

What are the contact details for BMS Medical Information?

To contact BMS for Medical Information, please telephone or email BMS Medical Information using the contact details below:

Tel: 1800 749 749
Email: medical.information@bms.com

Queries and Adverse Event reports (including cases of suspected or confirmed pregnancy or foetal exposure) can be reported at: www.globalbmsmedinfo.com.

How will BMS audit pharmacies registered for the Thalidomide BMS® Pregnancy Prevention Programme?

The terms of the thalidomide Marketing Authorisation include a **mandatory** requirement for annual feedback to be collected on the effectiveness of the Pregnancy Prevention Programme, at a national level. An agreement to assist with this process was a pre-condition for BMS approving the registration of pharmacies and thereby granting authorisation to procure thalidomide.

BMS have agreed with the HPRA that pharmacies can fulfil their obligations in this respect, by conducting a manual self-audit and reporting the results to BMS. This information will be provided, in an anonymised and aggregated format, to the HPRA. BMS will supply pharmacies with an audit pack, such that annual self-auditing of pharmacies and feedback of the audit results to BMS can occur.

It is therefore critical for pharmacies to ensure that all documentation associated with the Pregnancy Prevention Programme is completed accurately and that audit results are provided faithfully and diligently, in the interests of patient safety.

In addition, the Thalidomide BMS® Order Forms that registered pharmacies must complete to place an order will be forwarded to BMS Risk Management by UDD. This information will be provided, in an anonymised and aggregated format, to the HPRA annually.

It is therefore critical for pharmacies to ensure that Thalidomide BMS® Order Forms are completed accurately and fully.

14.0 Contact Details

Risk Management:
For information and questions on the Risk Management of BMS products, the Pregnancy Prevention Programme, pharmacy registrations and the use of the Prescription Authorisation Form.
Tel: 1800 992 427
Fax: 1800 992 429
Email: rmpukire@bms.com

Medical Information:
To report any Adverse Events or suspected pregnancies, or to obtain Medical Information on BMS products.
Tel: 1800 749 749
Email: medical.information@bms.com

Queries and Adverse Event reports (including cases of suspected or confirmed pregnancy or foetal exposure) can be reported at: www.globalbmsmedinfo.com.

Suspected Adverse Reactions (and cases of suspected or confirmed pregnancy or foetal exposure) can be reported via the HPRA Pharmacovigiliance website: www.hpra.ie

Data Protection:
Data Protection queries for the Thalidomide BMS® Pregnancy Prevention Programme can be sent to: eudpo@bms.com

Distributor for Thalidomide BMS® :
For product delivery enquiries.
United Drug Distribution (UDD)
United Drug House
Magna Business Park
Citywest Road
Dublin 24
Tel: 01 463 2478
Fax: 01 463 2404
Email: SpecialOrders@united-drug.com

Bristol Myers Squibb™

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