Thalidomide BMS®
(thalidomide)

Healthcare Professionals' Information Pack

IRELAND

Important Safety Information:
Healthcare Professionals involved in the prescribing or dispensing of thalidomide must read and understand the information contained within the Healthcare Professionals' Information Pack.

For complete safety information please refer to the Summary of Product Characteristics (SmPC) for Thalidomide BMS® available at the following website: Irish medicines compendium www.medicines.ie.

The Healthcare Professionals' Information Pack contains the information and materials needed for the prescribing and dispensing of thalidomide, 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 the Healthcare Professionals' Information Pack before prescribing or dispensing thalidomide for any patient.

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance at www.hpra.ie. Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com

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Bristol Myers Squibb™

Healthcare Professionals' Information Pack Contents

Healthcare Professional Information Guide

Patient Guide

Patient Pocket Information Card

Risk Awareness Forms

Prescription Authorisation Form

Community Pharmacy Dispensing Notification Form

Thalidomide BMS® Pharmacy Registration Form

Thalidomide BMS® Order Form

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

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.

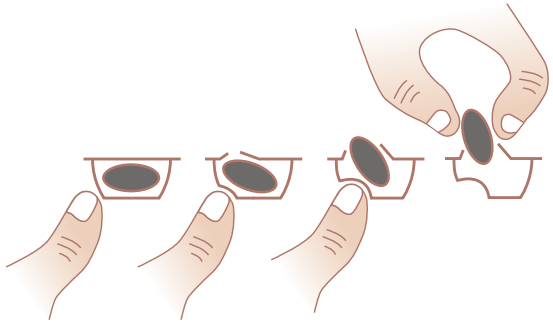
3.4.1 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

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.

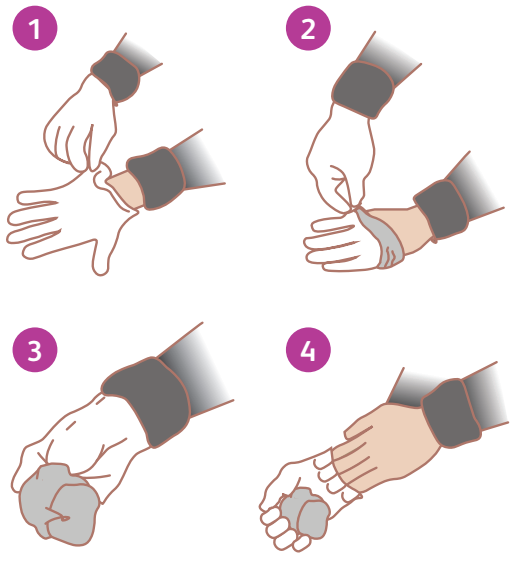
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air.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

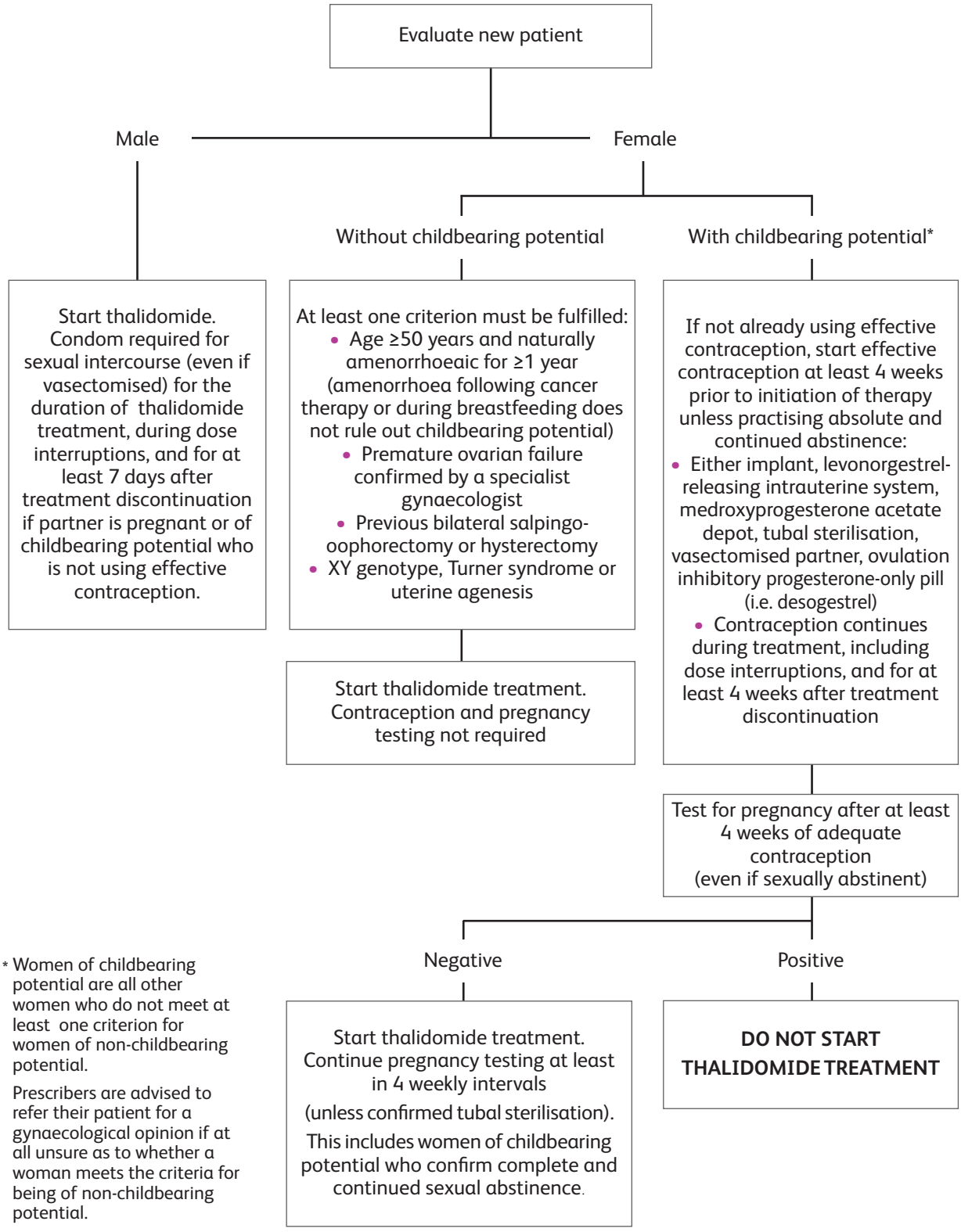
7.0 Reporting Adverse Events, Suspected and Confirmed Pregnancies, and Foetal Exposure

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

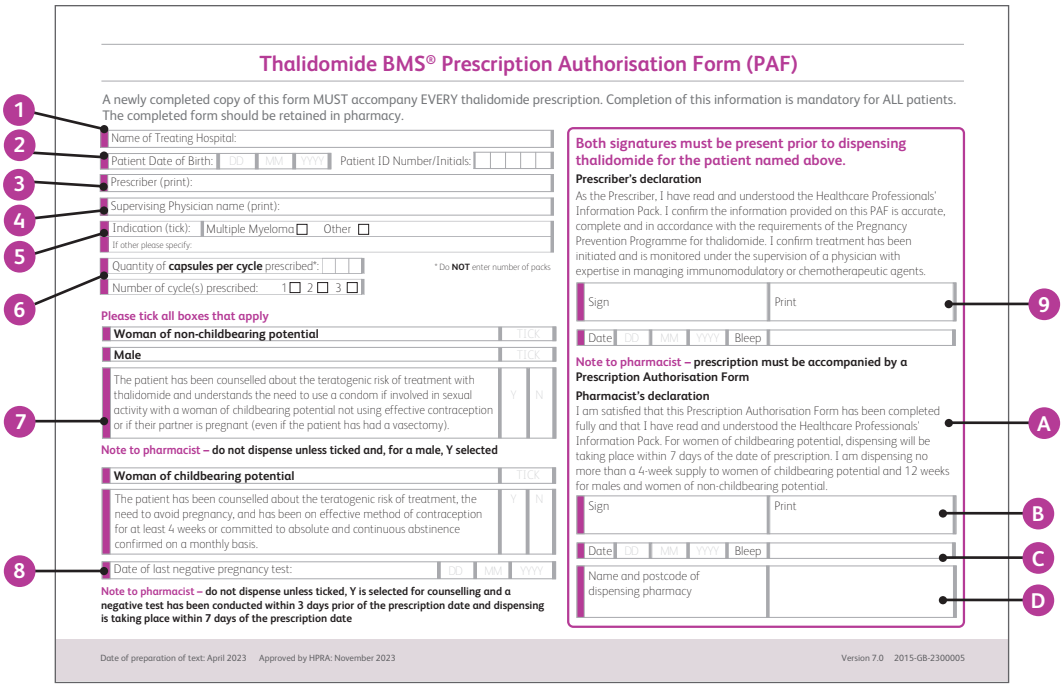


* Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.

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

Date of preparation of text: April 2023 Approved by HPRA: November 2023 Version 7.0 2015-GB-2300005

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.

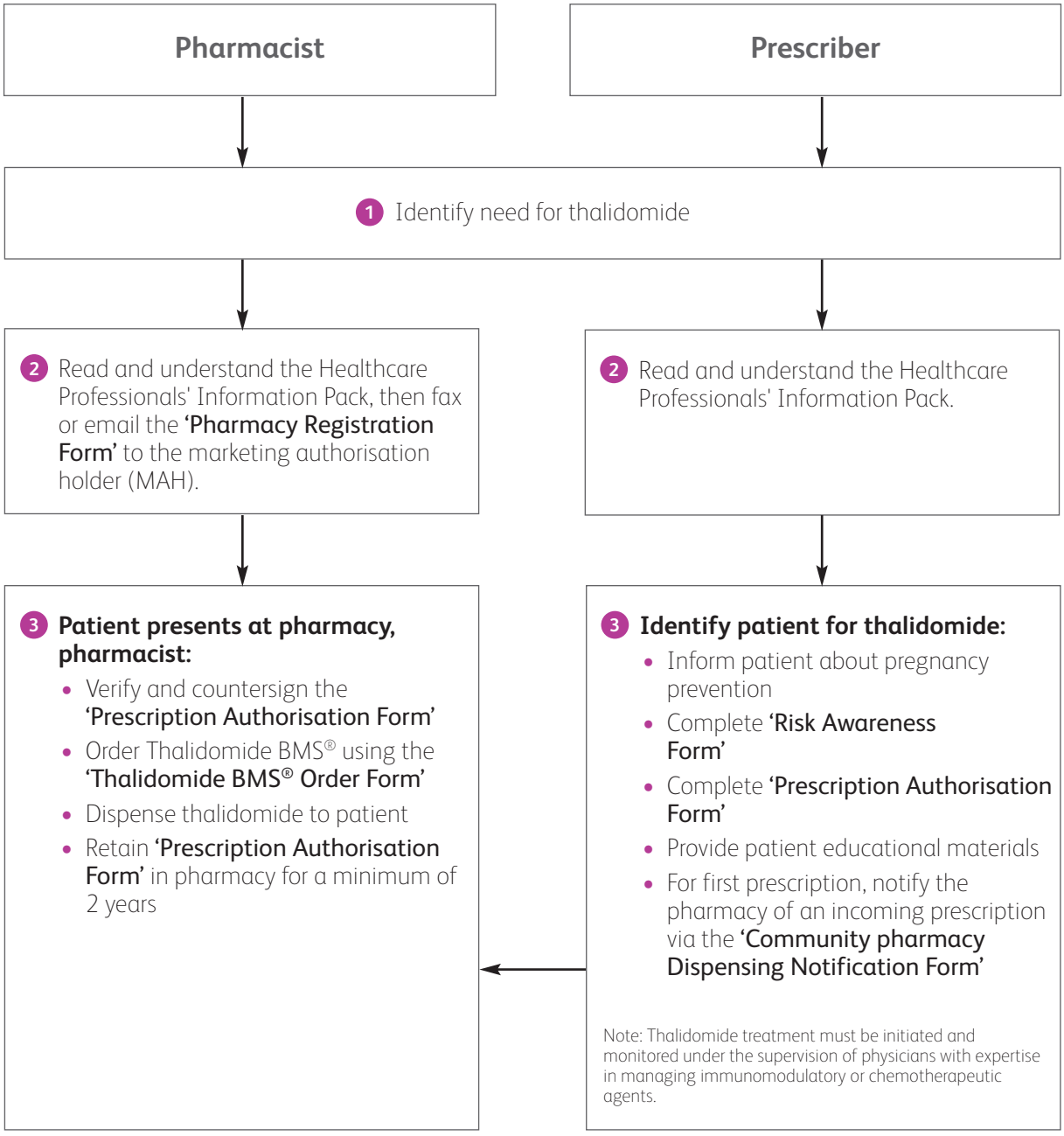
NB. Please ensure that all details are completed on this order form in full to ensure your order is processed appropriately and in a timely manner.

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™

Thalidomide BMS® (thalidomide) Pregnancy Prevention Programme Patient Guide

Information for patients taking thalidomide

IRELAND

Version 7.0

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly via HPRA Pharmacovigilance at www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.

This guide 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 what to expect from your treatment, and explain the risks and your responsibilities.

This guide provides education on thalidomide and will ensure that you know what to do before, during and after taking thalidomide.

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

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

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

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

Thalidomide 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.

Other side effects of thalidomide include: severe heart disease.

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

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

Please read this guide 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

Thalidomide belongs to a group of medicines known as 'Immunosuppressive' medicines. These work by acting on the cells involved in your immune system. The immune system is part of the body's defence which helps to fight illness and infection. Thalidomide also has anti-angiogenic properties. This means that it prevents the development of new blood vessels (angiogenesis). Angiogenesis is important for cancers because they need to produce new blood vessels in order to grow.

The Package Leaflet which came with your medicine tells you more about thalidomide.

This guide is part of the 'Thalidomide BMS® Pregnancy Prevention Programme', which is necessary because if thalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby. In the 1950s and 1960s thalidomide was prescribed to pregnant women as a sedative and to relieve morning sickness. As a result approximately 12,000 children were born with severe birth defects caused by thalidomide and approximately 5,000 are alive today.

The Thalidomide BMS® Pregnancy Prevention Programme is designed to prevent unborn babies being exposed to thalidomide. It makes sure you know what to do before, during and after taking the medicine:

1) Thalidomide can cause severe birth defects or death to an unborn baby.

2) Birth defects may include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems.

1) Thalidomide must never be used by women who are pregnant or by women who could become pregnant unless all the conditions of the Pregnancy Prevention Programme are met (these conditions are described in this guide).
2) As thalidomide is present in the seminal fluid of a man, as a precaution male patients will need to use a condom if engaged in sexual activity with a pregnant woman or a woman of childbearing potential who is not using effective contraception, even if the male patient has had a vasectomy. This must occur during treatment, during dose interruptions, and for at least 7 days after stopping thalidomide.
3) Male patients must not donate semen or sperm during treatment (including dose interruptions) and for at least 7 days following discontinuation of thalidomide.
4) Patients must not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.
5) Patients must not give thalidomide to another person and must return unused capsules to their pharmacist at the end treatment.

This guide contains important information about the Thalidomide BMS® Pregnancy Prevention Programme. You must read the information carefully, and before starting your treatment you should:

1) Understand the risks of thalidomide treatment. Please ensure you read the Package Leaflet before you use the medication as it contains information on the side effects that can occur with thalidomide.
2) Understand the instructions for taking thalidomide safely, including how to prevent pregnancy.
3) Understand what to expect during your initial and follow-up consultations with your prescriber.
4) Discuss with your prescriber who will have explained to you the risks of thalidomide treatment and specific instructions that you must follow.
5) Please make sure that you understand what your prescriber has told you before starting thalidomide.

If you don't understand something, please ask your prescriber to explain it again.

Thalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of thalidomide is that if taken during pregnancy, it can cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means thalidomide must never be taken by:

1) Women who are pregnant.

2) Women who could become pregnant, unless they follow the Thalidomide BMS® Pregnancy Prevention Programme.

Thalidomide and Other Possible Side Effects

Like all medicines, thalidomide 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 or 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 thalidomide treatment. Adverse events can be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance website: www.hpra.ie

Stop taking thalidomide and see a prescriber straightaway if you notice the following:

- Palpitations, chest pain (including if it spreads to the arms, neck, jaw, back or stomach), pressure in the chest, difficulty in breathing. Sweating, light headedness, dizziness, blurred vision and fatigue.

This is important because the above-mentioned symptoms may be indicators of more severe heart disease, such as a heart attack, which may need urgent medical attention.

Pregnancy Prevention Programme

You should tell your prescriber if you are pregnant, think you may be pregnant, or plan to become pregnant, as thalidomide can harm an unborn child. If you suspect pregnancy during treatment, discontinue immediately and inform your prescriber promptly.

1) Before starting thalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.
2) 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.
3) In order to ensure that an unborn baby is not exposed to thalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirements of the Pregnancy Prevention Programme. Women of childbearing potential will be informed NOT to become pregnant throughout the duration of treatment with thalidomide and for at least 4 weeks after stopping thalidomide.
4) If you are able to become pregnant and even if you agree and confirm every month that you will not engage in sexual activity, you will have a pregnancy test under medical supervision before treatment. These will be repeated every 4 weeks during treatment and 4 weeks after the treatment has finished unless it is confirmed that you have had a tubal sterilisation.
5) 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 4 weeks before starting treatment, during treatment, including dose interruptions, and until 4 weeks after stopping treatment unless you commit to absolute and continuous abstinence confirmed on a monthly basis. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with thalidomide. Therefore, it is essential to discuss this with your prescriber and if necessary, your hospital team can refer you to a specialist for advice on contraception.
6) If you suspect you are pregnant at any time whilst taking thalidomide or in the 4 weeks after stopping, you must stop thalidomide 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 prescribers for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice presented in the next section:

1) You are at least 50 years old, and naturally amenorrhoeic for at least 1 year (amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential)

2) Your womb has been removed (hysterectomy)

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

4) You have premature ovarian failure, confirmed by a specialist gynaecologist.

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

If you believe that you are a woman of childbearing potential then please inform your prescriber straight away. Your prescriber may refer you for a gynaecological opinion if they are unsure whether you meet the criteria for being of non-childbearing potential.

Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in this section.

Women of Childbearing Potential

Prior to starting initial treatment your prescriber will talk to you about the contraceptive measures that you must follow and will document that you have been fully informed of and understand the risk of teratogenicity and other adverse drug reactions associated with the use of thalidomide on the Risk Awareness Form. If you could become pregnant you must use at least one effective method of contraception, or commit to absolute and continuous abstinence, which you will need to confirm on a monthly basis. If you are able to become pregnant, your prescriber will make sure that you have a pregnancy test:

1) At least 4 weeks before starting thalidomide treatment.

2) Every 4 weeks during treatment, even during treatment interruptions.

3) Until 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 thalidomide. It is essential therefore that you discuss this with your prescriber.

It is important that you do not change or stop contraceptive (birth control) methods without talking to your prescriber first.

If you are pregnant or trying to become pregnant, you must not take thalidomide. If you are able to become pregnant, your prescriber will perform regular pregnancy tests to confirm that you are not pregnant before taking thalidomide.

It is important that you understand and follow **appropriate methods of contraception** and **pregnancy testing** information described.

1) You must have been using an effective contraceptive method for at least 4 weeks before thalidomide can be prescribed. You will need to continue to use an effective contraceptive method during treatment, even during dose interruptions, and until at least 4 weeks after stopping treatment.
2) Your prescriber will perform the pregnancy test during the consultation when thalidomide is prescribed, or in the previous three days.
3) A pregnancy test will take place at least every 4 weeks (except in the case of confirmed tubal sterilisation) even if you think there is no chance you have become pregnant since your last test.
4) During treatment if you miss or think you have missed a period, or you have any unusual menstrual bleeding, you must stop treatment and tell your prescriber straightaway.
5) You must stop treatment and inform your doctor straight away if you have heterosexual intercourse without using an effective method of contraception.
6) Talk to your prescriber before changing or stopping any method of contraception.
7) A pregnancy test will take place at least 4 weeks after stopping treatment.

If you think you are pregnant, stop taking thalidomide and contact your prescriber straightaway.

Do not take Thalidomide BMS® if you are pregnant or think you may be pregnant or are planning to become pregnant, **as Thalidomide BMS® causes birth defects and foetal death.**

Males

Thalidomide is present in seminal fluid. Prior to starting initial treatment your prescriber will talk to you about the contraceptive measures that you must follow if you have a female partner who is pregnant or who is able to become pregnant, as you must protect her against any exposure to thalidomide. Your prescriber will document that you have been fully informed of and understand the risk of teratogenicity and other adverse drug reactions associated with the use of thalidomide on the Risk Awareness Form. This means that if your partner is pregnant, or is able to get pregnant and not using an effective method of contraception, you must use condoms every time you have heterosexual intercourse:

1) During treatment, even during dose interruptions.

2) Until at least 7 days after stopping treatment.

3) Even if you have had a vasectomy as seminal fluid may still contain thalidomide in the absence of spermatozoa.

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

You must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping treatment.

Women of Non-Childbearing Potential

In order to ensure that an unborn baby is not exposed to thalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become pregnant, and you are aware about the restrictions regarding blood donation, sharing medication and safe disposal of unwanted capsules.

Thalidomide 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 Risk Awareness Form, which confirms that while taking thalidomide:

1) You understand the risk 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.
2) If you are able to become pregnant you will follow the necessary requirements to prevent pregnancy.
3) You understand the other important safety messages.
4) As a male patient, you understand the need to use condoms during treatment (including dose interruptions) and for at least 7 days after stopping thalidomide 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.

Receiving Your Prescription

Your prescriber must complete a 'Prescription Authorisation Form' in addition to your prescription, which will be given to you to present at your nominated pharmacy each time you are prescribed thalidomide. This form confirms that all of the Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to ordering and dispensing your thalidomide.

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. A negative pregnancy test must also be confirmed on the prescription authorisation form before thalidomide can be dispensed.

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.

Safety Measures During Treatment

1) Please remember that your thalidomide must only be used by you. Do not share your medicine with anyone else, even if they have similar symptoms to you.
2) Store your thalidomide capsules safely, so no one else could take them by accident.
3) Keep thalidomide out of reach and sight of children.
4) You must not donate blood, and men must also not donate semen or sperm, while being treated with thalidomide, (including dose interruptions), and for at least 7 days after stopping treatment.

What to do if You Have Taken More Than the Prescribed Dose of Thalidomide

If you take more thalidomide than you should, talk to a prescriber or go to a hospital straightaway. If possible, take the medicine pack and this guide with you.

What to do if You Forget to Take Thalidomide

1) If you forget to take thalidomide at your regular time and less than 12 hours have passed: take your capsules immediately.

2) If more than 12 hours have passed: do not take your capsules. Take your next capsules at the usual time the next day.

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 thalidomide and any other medications.

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 themselves to take their medications.

- Your prescriber will prescribe a dose of thalidomide suited to you.
- When thalidomide is used to treat Multiple Myeloma, thalidomide is used in combination with two other medications (melphalan and prednisone).

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 prescriber has prescribed. If in doubt, ask your prescriber or pharmacist for advice.
- Thalidomide capsules should be swallowed whole, with a glass of water.
- Thalidomide should be taken as a single dose before going to bed. This will make you less likely to feel sleepy at other times.
- Thalidomide can be taken with or without food.

End of Treatment Requirements

After completing your thalidomide treatment, it is important that:

1) You return any unused thalidomide capsules to your pharmacist.

2) You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

1) Continue using your effective method of contraception for at least 4 weeks after the end of treatment.

2) You have to undergo a final pregnancy test at least 4 weeks after the end of treatment.

Additional advice for male patients:

1) If you have been using condoms a method of contraception, you must continue doing so for at least 7 days.

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

3) Do not donate semen or sperm for at least 7 days after the end of treatment.

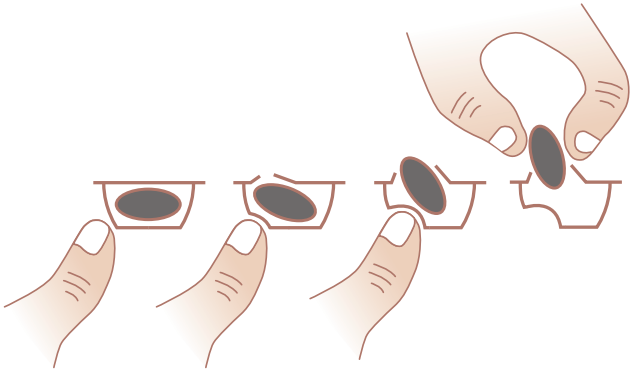
Points to Consider for Handling the Medicinal Product: For Patients, Family Members and Caregivers

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

Keep the blisters with the capsules in the original pack.

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

Healthcare professionals, family members 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 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 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.
- Do not give thalidomide 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.

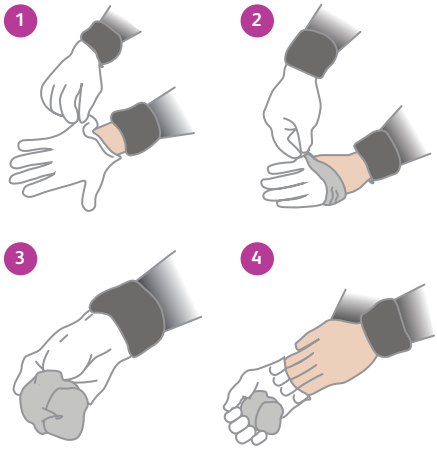
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add 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 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 drug powder makes contact with one or both of your eyes, remove and discard any contact lenses in use. Then, thoroughly flush eyes with 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.

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.

Personal Notes

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

Checklist

Please use this checklist to confirm that you have understood all of the important information regarding your thalidomide treatment.

All Patients

- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking thalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking thalidomide.
- ☐ Yes, I have understood that I must not donate blood during treatment (including dose interruptions) and for at least 7 days after stopping treatment.
- ☐ Yes, I understand that I need to sign the Risk Awareness Form before starting treatment.
- ☐ Yes, I have understood that I should never share thalidomide with anyone else.
- ☐ Yes, I have understood that I should always return any unused capsules to the pharmacist for safe disposal as soon as possible.

Male Patients

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

Female patients who can become pregnant

- ☐ Yes, I have received and understood the contraceptive advice.
- ☐ Yes, I will use one effective method of contraception for at least 4 weeks before starting thalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped thalidomide treatment.
- ☐ 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).

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

This Patient Guide is produced by BMS.

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

Data Protection:

Data Protection queries can be sent to: eudpo@bms.com


Bristol Myers Squibb™

Information for Patients and Healthcare Professionals:

Thalidomide can 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 prior to starting treatment and 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 symptom that causes concern.

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

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.

* Woman of childbearing potential

† Woman of non-childbearing potential

Information for Healthcare Professionals:

Prescription Details:

This patient is receiving thalidomide for treatment of:

Emergency Contact Information

Emergency Prescriber Contact:

Telephone number during office hours:

Telephone number after office hours:

Thalidomide BMS® (thalidomide) Pregnancy Prevention Programme

Male Risk Awareness Form

IRELAND

Version 7.0

RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF THALIDOMIDE BMS®

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

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

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

Warning: 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 Pregnancy Prevention Programme are met. The conditions of the Pregnancy Prevention Programme must be fulfilled for all male and female patients.

If thalidomide is taken during pregnancy it can cause severe life-threatening birth defects or death to an unborn baby.

Patient Details

Patient's First Name:																							
Patient's Last Name:																							

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

Did you inform your patient:	Male
1) Of the need to avoid foetal exposure.	*Tick*
2) To not share the medicinal product with any other person.	*Tick*
3) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.	*Tick*
4) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
5) Of the effective contraceptive measures he or his female partner can use.	*Tick*
6) That thalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy) throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment.	*Tick*
7) That if his partner becomes pregnant, he should inform his treating prescriber immediately, his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	*Tick*
8) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.	*Tick*
9) Of the hazards and necessary precautions associated with use of the thalidomide.	*Tick*

Can you confirm your patient:

Is capable of complying with contraceptive measures?	*YES*	*NO*

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 contraception.	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 thalidomide, especially the risks to women of childbearing potential.

I will comply with all my obligations and responsibilities as the prescriber of thalidomide.

Prescriber's First Name :																					
Prescriber's Last Name:																					

Prescriber's Signature:		Date:	DD	MM	YYYY

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

I have been told by my prescriber that I must NEVER have unprotected sexual contact with women who are pregnant or may become pregnant, while I am taking thalidomide and for 1 week after stopping treatment.	Patient initials
I understand that severe birth defects can occur with the use of thalidomide. 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 thalidomide.	Patient initials
I understand that thalidomide 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 thalidomide 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 thalidomide or within 7 days after I have stopped taking thalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that thalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the thalidomide Patient Guide and understand the contents, including the information about other possible health problems (side effects) from thalidomide.	Patient initials
I know that I cannot donate blood while taking thalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused thalidomide 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 know that I cannot donate semen or sperm while taking thalidomide, during dose interruptions and for at least 7 days after stopping treatment.	Patient initials
I understand that my prescriber will provide me with a 'Prescription Authorisation Form' with each thalidomide prescription, and that I must provide this to my pharmacy.	Patient initials
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure thalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of thalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Thalidomide BMS® Pregnancy Prevention Programme. I agree that my prescriber can initiate my treatment with thalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF), Order Form) will be processed by Bristol-Myers Squibb Pharma EEIG ("BMS"), as the marketing authorisation holder of Thalidomide BMS® and the distributor for the purpose(s) of managing the Pregnancy Prevention Programme.

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

Should you have any queries in relation to the use of your personal data please contact your doctor or BMS at: eudpo@bms.com. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	*DD*	*MM*	*YYYY*

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer 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 thalidomide.

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

Bristol Myers Squibb™

Thalidomide BMS® (thalidomide) Pregnancy Prevention Programme

Woman of Childbearing Potential Risk Awareness Form

IRELAND

Version 7.0

RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF THALIDOMIDE BMS®

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

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

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

Warning: 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 Pregnancy Prevention Programme are met. The conditions of the Pregnancy Prevention Programme must be fulfilled for all male and female patients.

If thalidomide is taken during pregnancy it can cause severe life-threatening birth defects or death to an unborn baby.

Patient Details

Patient's First Name:																						
Patient's Last Name:																						

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

Did you inform your patient:	Woman of Childbearing Potential
1) Of the expected teratogenic risk to the unborn child and the need to avoid foetal exposure.	*Tick*
2) That if she is pregnant or plans to be, she must not take thalidomide.	*Tick*
3) Of the effective contraception she can use.	*Tick*
4) Of the need to avoid thalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment.	*Tick*
5) That if she needs to change or stop using her method of contraception she should inform: a) the prescriber prescribing her contraception that she is taking thalidomide b) the prescriber prescribing thalidomide that she has stopped or changed her method of contraception.	*Tick*
6) Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment.	*Tick*
7) Of the need to stop thalidomide immediately upon suspicion of pregnancy.	*Tick*
8) Of the need to contact their prescriber immediately upon suspicion of pregnancy.	*Tick*
9) To not share the medicinal product with any other person.	
10) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.	*Tick*
11) That even if patient has amenorrhoea they must comply with advice on contraception.	*Tick*
12) Of the hazards and necessary precautions associated with use of the thalidomide.	*Tick*
13) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*

Can you confirm your patient:

1) Was referred to a contraceptive consultant, if required?	YES	NO
2) Is capable of complying with contraceptive measures?	YES	NO
3) Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	YES	NO
4) Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	YES	NO

Contraceptive Referral

Contraceptive referral made on:	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 absolute and continuous abstinence	Tick

Pregnancy Test

Date of last negative pregnancy test, prior to treatment initiation:	DD	MM	YYYY

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 COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

Prescriber Confirmation

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

I will comply with all my obligations and responsibilities as the prescriber of thalidomide.

Prescriber's First Name :																					
Prescriber's Last Name:																					

Prescriber's 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 can occur with the use of thalidomide. 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 thalidomide.	*Patient initials*
I understand that I must not take thalidomide if I am pregnant or plan to become pregnant.	*Patient initials*
I understand that I must use 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 prescriber prescribing my contraception method and the prescriber prescribing my thalidomide.	*Patient initials*
I understand that before starting the thalidomide 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 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 thalidomide and inform my treating prescriber immediately upon suspicion of pregnancy while taking this drug (including dose interruptions); 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 thalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the thalidomide Patient Guide and understand the contents, including the information about other possible health problems (side effects) from thalidomide.	*Patient initials*
I know that I cannot donate blood while taking thalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused thalidomide to my pharmacy at the end of my treatment.	*Patient initials*
I understand that even if I have amenorrhoea I must comply with advice on contraception.	*Patient initials*
I understand that my prescriber will provide me with a 'Prescription Authorisation Form' with each thalidomide prescription, and that I must provide this to my pharmacy.	*Patient initials*
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure thalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of thalidomide.	*Patient initials*

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Thalidomide BMS® Pregnancy Prevention Programme. I agree that my prescriber can initiate my treatment with thalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF) or Order Form) will be processed by Bristol-Myers Squibb Pharma EEIG ("BMS"), as the marketing authorisation holder of Thalidomide BMS® and the distributor for the purpose(s) of managing the Pregnancy Prevention Programme.

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

Should you have any queries in relation to the use of your personal data please contact your doctor or BMS at: eudpo@bms.com. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority

Patient Signature:		Date:	*DD*	*MM*	*YYYY*

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer 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 thalidomide.

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

Bristol Myers Squibb™

Thalidomide BMS® (thalidomide) Pregnancy Prevention Programme

Woman of Non-Childbearing Potential Risk Awareness Form

IRELAND

Version 7.0

RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF THALIDOMIDE BMS®

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

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

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

Warning: 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 Pregnancy Prevention Programme are met. The conditions of the Pregnancy Prevention Programme must be fulfilled for all male and female patients.

If thalidomide is taken during pregnancy it can cause severe life-threatening birth defects or death to an unborn baby.

Patient Details

Patient's First Name:																							
Patient's Last Name:																							

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

Did you inform your patient:	Woman of Non-Childbearing Potential
1) To not share the medicinal product with any other person.	*Tick*
2) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of thalidomide.	*Tick*
3) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
4) Of the hazards and necessary precautions associated with use of the thalidomide.	*Tick*

Prescriber Confirmation

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

I will comply with all my obligations and responsibilities as the prescriber of thalidomide.

Prescriber's First Name :																							
Prescriber's 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 can occur with the use of thalidomide. 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 thalidomide.	Patient initials
I understand that thalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the thalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) from thalidomide.	Patient initials
I know that I cannot donate blood while taking thalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused thalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I understand that my prescriber will provide me with a 'Prescription Authorisation Form' with each thalidomide prescription, and that I must provide this to my pharmacy.	Patient initials
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure thalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of thalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the Thalidomide BMS® Pregnancy Prevention Programme. I agree that my prescriber can initiate my treatment with thalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF) or Order Form) will be processed by Bristol-Myers Squibb Pharma EEIG ("BMS"), as the marketing authorisation holder of Thalidomide BMS® and the distributor for the purpose(s) of managing the Pregnancy Prevention Programme.

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Patient Signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer 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 thalidomide.

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

Bristol Myers Squibb™

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.

Name of Treating Hospital:

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

Prescriber (print):

Supervising Physician name (print):

Indication (tick): Multiple Myeloma ☐ Other ☐

If other please specify:

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

Woman of non-childbearing potential	TICK
Male	TICK
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).	Y / N

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

Woman of childbearing potential	TICK
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.	Y / N

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.

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.

Sign	Print

Date DD MM YYYY Bleep

Name and postcode of dispensing pharmacy

Thalidomide BMS® (thalidomide) Community Pharmacy Dispensing Notification Form

1. To the prescriber

This is a notification form to advise the nominated community pharmacy that they will soon be receiving a High Tech Prescription for thalidomide for your patient. This will enable the community pharmacy to register with Bristol-Myers Squibb (BMS) and subsequently be able to order and dispense thalidomide for your patient.

Please complete the prescriber section below upon the first occasion that the patient is being prescribed thalidomide and email or fax to the **Nominated Community Pharmacy** on the details below.

Prescriber Details (Please print)	
Date of Prescription:	Patient Identifier:
Full Name of Prescriber:	
Hospital Name and Address: (Please print) _____ _____ _____ _____	Hospital stamp
Contact Phone Number:	

Email or Fax to Nominated Pharmacy
Email:
Fax Number:
Nominated Pharmacy Name and Address: (Please print) _____ _____ _____ _____
Date:

2. To the Nominated Community Pharmacy

The prescriber named above has prescribed thalidomide for their patient. The patient has nominated your pharmacy to dispense the prescription.

Pharmacies dispensing Thalidomide BMS® must be registered with BMS.
If you are not already registered, please contact BMS on 1800 992 427 and they will forward you the relevant information.

Once you are registered, you will be able to order Thalidomide BMS® from UDD using the Thalidomide BMS® Order Forms available inside the Healthcare Professionals' Information Pack which you will receive from BMS Risk Management.

If you have any questions regarding this form or require further information about thalidomide please contact BMS Risk Management on 1800 992 427.

Thalidomide BMS® (thalidomide) Pharmacy Registration Form

To be completed by the Chief/Superintendent Pharmacist or appointed deputy pharmacist.

Pharmacy name (include all legal/trading names):	
Chief/Superintendent Pharmacist (or appointed deputy pharmacist):	
Contact telephone number:	
Email:	
PSI Registration Number:	
Dispensing Pharmacy Address:	Delivery Address (if different):
Eircode:	Eircode:
Tel:	Tel:
Fax:	Fax:
Email:	Email:
Ordering Address (if different to delivery address):	
Eircode:	

On behalf of ..... [pharmacy name], I agree to implement the following risk minimisation procedures when dealing with prescriptions for thalidomide as specified by Bristol-Myers Squibb (BMS) in the Thalidomide BMS® Healthcare Professionals' Information Pack.

1	I have read and understood the Thalidomide BMS® Healthcare Professionals' Information Pack.	TICK
2	All pharmacists who dispense Thalidomide BMS® will have read and understood the Thalidomide BMS® Healthcare Professionals' Information Pack.	TICK
3	If supplied with Thalidomide BMS®, it will only be used for the purpose of dispensing the product by the Pregnancy Prevention Programme registered pharmacy to the patient.	TICK
4	Prescriptions for Thalidomide BMS® will be dispensed only if accompanied by a completed Thalidomide BMS® Prescription Authorisation Form.	TICK
5	The pharmacist dispensing Thalidomide BMS® will check each prescription and Thalidomide BMS® Prescription Authorisation Form for completeness and countersign the authorisation form prior to dispensing.	TICK
6	Pharmacies must undertake the **mandatory** annual self-audit of the Thalidomide BMS® Prescription Authorisation Forms. Compliance with these procedures will be audited by the chief/superintendent pharmacist or appointed deputy pharmacist at least annually. Audit results will be made available to BMS so that their obligation to report to the regulatory agencies on the overall effectiveness of the programme can be met.	TICK
7	Thalidomide BMS® will be dispensed, checked and stored according to our standard documented procedures for oral anti-cancer medicines.	TICK
8	Dispensing will be limited to no more than a 4-week supply for women of childbearing potential, and 12 weeks for males and women of non-childbearing potential.	TICK
9	Dispensing to women of childbearing potential should occur within 7 days of the prescription.	TICK
10	After dispensing, Thalidomide BMS® Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years.	TICK
11	I will notify BMS of any change in contact details.	TICK

I confirm that I am ordering on behalf of a registered pharmacy and that thalidomide will be dispensed in accordance with the risk minimisation procedures for thalidomide, as specified by Bristol-Myers Squibb in the Thalidomide BMS® Healthcare Professional Information Guide.

Sign:				
Print:	Date:	DD	MM	YYYY

Fax the completed forms to BMS on 1800 992 429 or email to rmpukire@bms.com

Thalidomide BMS® (thalidomide) Order Form Ireland

Orders cannot be processed unless this form is fully completed and signed. The completed Order Form should be emailed to United Drug Distribution (UDD), for the attention of UDD Customer Service **SpecialOrders@united-drug.com** or **Faxed to 01 463 2404**. Orders received before **13:30 Monday-Friday** will be delivered the next working day (note there are no deliveries on Saturdays).

For queries about your order please email **SpecialOrders@united-drug.com** or **Telephone 01 463 2478.** Please ensure all data is recorded in Black or Blue ink. Prescription Authorisation Forms and Prescriptions should not be sent to United Drug.

Pharmacy Details

Ordered by: (Please print full name and position e.g. Irish registered pharmacist/technician)

Pharmacy Name & address: (Please print)

Pharmacy Stamp

Pharmacy Telephone:

Please indicate your nominated Wholesaler: (Please tick)

UD ☐ Dublin ☐ Ballina ☐ Limerick

UD Wholesale Account Number:

Patient Details

Prescriber (Please print)

Treating Hospital

Indication

Patient Date of Birth

Male TICK

Woman of childbearing potential (WCBP) TICK

Woman of non-childbearing potential (WNCBP) TICK

Dose of thalidomide being prescribed

Date of prescription

Product Description	Strength	Quantity required
Thalidomide BMS® Capsules	50mg	

Comments

Is this the 1st, 2nd or 3rd dispensing of this prescription: 1st ☐ 2nd ☐ 3rd ☐

Total Supply Prescribed: 4-weeks ☐ 8-weeks ☐ 12-weeks ☐ Other - specify_____

I confirm that I am ordering on behalf of a registered pharmacy and that thalidomide will be dispensed in accordance with the risk minimisation procedures for thalidomide, as specified by BMS in the Thalidomide BMS® Healthcare Professionals' Information Pack.

I confirm that treatment lengths will be limited to a maximum 4 weeks supply for women of childbearing potential and a maximum of 12 weeks for males and women of non-childbearing potential patients. For women of childbearing potential dispensing will be within 7 days of the date of prescription

Sign

Date

Telephone

Print

FOR INTERNAL USE ONLY:

Sales Order:_____ Date: _____ Initials: _____