Revlimid®▼
(lenalidomide)

Healthcare Professionals' Information Pack

IRELAND

Important Safety Information:
Healthcare Professionals involved in the prescribing or dispensing of lenalidomide 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 lenalidomide 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 lenalidomide, including information about the Pregnancy Prevention Programme.

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

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

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

Date of preparation of text: October 2023
Approved by HPRA: November 2023

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Bristol Myers Squibb™

Healthcare Professionals' Information Pack Contents

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

Date of preparation of text: May 2023
Approved by HPRA: November 2023

Contents

1.0 Introduction

This guide contains the information needed for the prescribing and dispensing of lenalidomide, including information about the Pregnancy Prevention Programme (PPP) and important safety information. This guide will help you understand these precautions and make sure you know what to do before prescribing and dispensing lenalidomide.

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

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

Lenalidomide Pregnancy Prevention Programme:

Lenalidomide is an immunomodulating medicinal product.

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby. This programme is designed to make sure that unborn babies are not exposed to lenalidomide. It will provide you with information about how to follow the programme and explain your responsibilities. It is a requirement of the PPP that all Healthcare Professionals (HCP) ensure that they have read and understood the Healthcare Professionals' Information Pack before prescribing or dispensing lenalidomide for any patient.

For full information regarding the requirements of the PPP, as well as safety information, side effects and recommended precautions please refer to the Revlimid® Summary of Product Characteristics (SmPC). This can be found on the following website: www.medicines.ie.

When lenalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to initiation of treatment. Please refer to the SmPC for further information. This can be found on the following websites: www.medicines.ie and www.hpra.ie.

2.0 Lenalidomide Pregnancy Prevention Programme

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. An embryofoetal development study has been conducted in monkeys administered with lenalidomide at doses up to 4mg/kg/day.

Findings from this study showed that lenalidomide produced external malformations (short limbs, bent digits, wrist and/or tail, supernumerary or absent digits) in the offspring of female monkeys who received the drug during pregnancy. Thalidomide produced similar types of malformations in the same study.

If lenalidomide is taken during pregnancy, a teratogenic effect in humans is expected. Lenalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this HCP Information Guide are met.

- 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 lenalidomide for any patient.
- You must ensure that your patient fully understands what you have told them about lenalidomide before starting the treatment. All men and all women of childbearing potential should undergo, at treatment initiation, counselling of the need to avoid pregnancy (this must be documented via a Risk Awareness Form which is available for this purpose).
- 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 and handling of lenalidomide.
- Patients must be provided with the appropriate Patient Guide, 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 Professionals' Information Pack.

All of the Revlimid® Pregnancy Prevention Programme materials are available electronically on the website www.hpra.ie (enter 'Revlimid' 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 Revlimid® will only be allowed from pharmacies registered with BMS. BMS will not authorise supply of Revlimid® to pharmacies that are not registered.

The following are core requirements of the Pregnancy Prevention Programme:

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

3.0 Safety Advice to Avoid Foetal Exposure

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

* 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 lenalidomide 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 lenalidomide, 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 lenalidomide therapy, and even in case of dose interruption **or**
  - commit to absolute and continuous abstinence confirmed on a monthly basis

  AND

  - have a medically supervised negative pregnancy test 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 lenalidomide 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 taking lenalidomide in combination therapy, and to a lesser extent in patients with multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma taking lenalidomide monotherapy, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, the patient should switch to at least one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

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

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

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

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

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

If a woman of childbearing potential has sexual contact without using an effective contraceptive method while taking lenalidomide, 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 Revlimid®:

- **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 lenalidomide, foetal exposure should be avoided.

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

Lenalidomide is present in human semen. As a precaution, all male patients taking lenalidomide, including those who have had a vasectomy as seminal fluid may still contain lenalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential and has no contraception.

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

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

If the partner of a male patient taking Revlimid® 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 to 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 lenalidomide. If they discontinue therapy, or if there are any unused capsules at the end of their treatment, they must return any unused lenalidomide to the pharmacist.

They must also understand that their lenalidomide 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 Patients, 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.

Please Note: the method of removal of the capsule from the blister may differ between different lenalidomide products. Please refer to the SmPC for the lenalidomide product you are handling for specific handling advice.

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.

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 below for further guidance.

When Handling the Medicinal Product Use the Following Precautions to Prevent Potential Exposure if You are a Healthcare Professional or Caregiver

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see below).
- Place gloves in 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

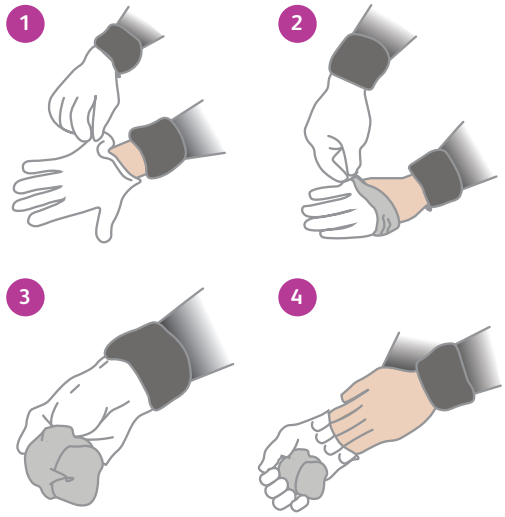
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. 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; Email: 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 the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist.

Proper Technique for Removing Gloves:

- Grasp outside edge near wrist (1)
- Peel away from hand, turning glove inside-out (2)
- Hold in opposite gloved hand (3)
- Slide ungloved finger under the wrist of the remaining glove, 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 Lenalidomide

Lenalidomide 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 treatment of 4 weeks according to the approved indications' dosing regimens, and prescriptions for all other patients can be for a maximum duration of treatment 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 lenalidomide in accordance with the measures described in this guide and the SmPC, which can be found on the following website: www.medicines.ie.
- Obtain their written confirmation (using the Risk Awareness Form for the appropriate patient category) that they have received and understood this information, and provide the patient with a copy.
- Ensure that your patient is using an effective method of contraception, if relevant.
- Perform a pregnancy test (if appropriate) before initiating treatment.

Community pharmacy notification

A lenalidomide 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 lenalidomide. The lenalidomide 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 lenalidomide.

4.3 Subsequent Prescriptions

- Before issuing subsequent prescriptions you must:
  - Ensure your patient continues to understand the risks of lenalidomide 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 or submit electronically to the pharmacy with each lenalidomide prescription.

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

4.4 Prescription Authorisation Form

Every prescription for lenalidomide must be accompanied by a completed Prescription Authorisation Form (PAF).

The prescriber must confirm on the prescription authorisation form:

- Patient initials, date of birth and the indication for which lenalidomide is being prescribed.
- Name of treating hospital, prescriber name, supervising physician name, signature and date.
- Confirmation that they have provided counselling on the teratogenic risk of lenalidomide and the required contraceptive measures for women of childbearing potential and male patients.
- 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 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 lenalidomide.
- 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 lenalidomide. The patient must return to their prescriber for every repeat prescription of lenalidomide.

When completing the Prescription Authorisation Form the pharmacist must confirm:

- 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 has read and understood the contents of the Healthcare Professionals' Information Pack.
- That the pharmacist is dispensing the appropriate supply for the patient category.

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

The Prescription Authorisation Form should be retained with the High Technology Prescription in the pharmacy for a minimum of 2 years.

4.5 Dispensing Revlimid®

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense Revlimid® are registered with BMS. Registration involves reading 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 Revlimid.

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

Revlimid® 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.

Community pharmacy notification and registration

A lenalidomide 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 High Tech Prescription for lenalidomide for your patient. The pharmacy will need to register with the lenalidomide Pregnancy Prevention Programme for the manufacturer of any products it will be dispensing prior to being able to order those lenalidomide products for your patient and dispense them. If the nominated pharmacy is not already authorised to supply Revlimid®, it must first contact BMS to register with them using the Revlimid® Pharmacy Registration Form. BMS will then send the pharmacy the relevant documentation if not already received.

Ordering of lenalidomide

The pharmacy must be registered with BMS to order Revlimid® and must also use a specific Revlimid® 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 Revlimid®.

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 lenalidomide 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 lenalidomide can be for a maximum duration of treatment of 4 weeks and continuation of treatment requires a new prescription.

For males and women of non-childbearing potential

- Prescriptions of lenalidomide should be limited to a maximum duration of 12 consecutive weeks and continuation of treatment requires a new prescription.

For all patients

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

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

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

The terms of the Revlimid® 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 lenalidomide 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 Revlimid® 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 Lenalidomide

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

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

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

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

6.2 Second Primary Malignancies

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

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

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

6.3 Progression to Acute Myeloid Leukaemia in Low- and Int-1-Risk MDS Patients

Baseline variables including complex cytogenetics and TP53 mutation are associated with progression to AML in subjects who are transfusion dependent and have a deletion (5q) abnormality. (see Section 4.4 of the SmPC).

6.4 Disposal of Unwanted Medicine

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

6.5 Blood Donation

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

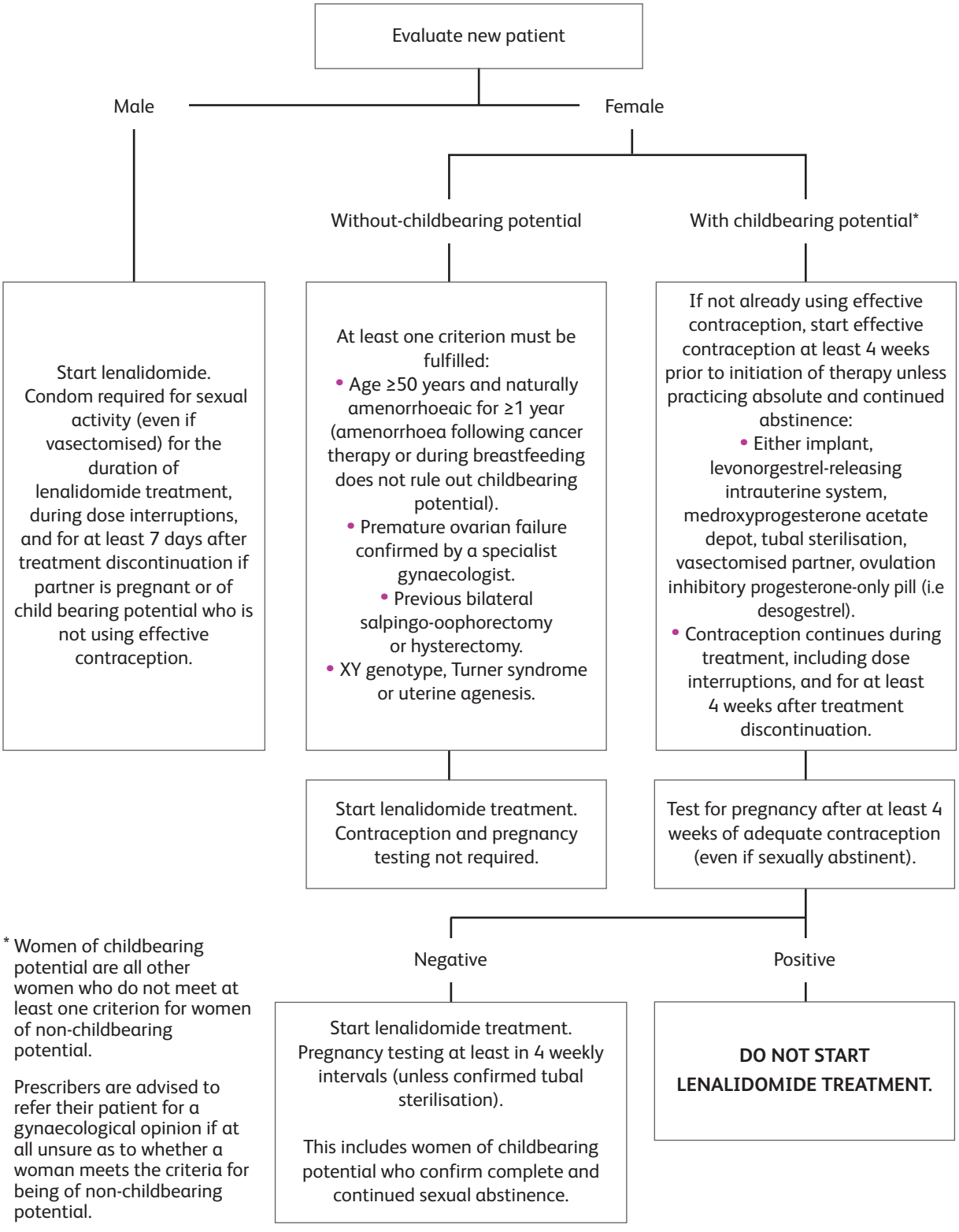
7.0 Reporting Adverse Events, Suspected and Confirmed Pregnancies, and Foetal Exposures

The safe use of Revlimid® 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).

Suspected adverse reactions (and cases of suspected or confirmed pregnancy or foetal exposure) can also be reported via the HPRA Pharmacovigilance website: www.hpra.ie.

8.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm

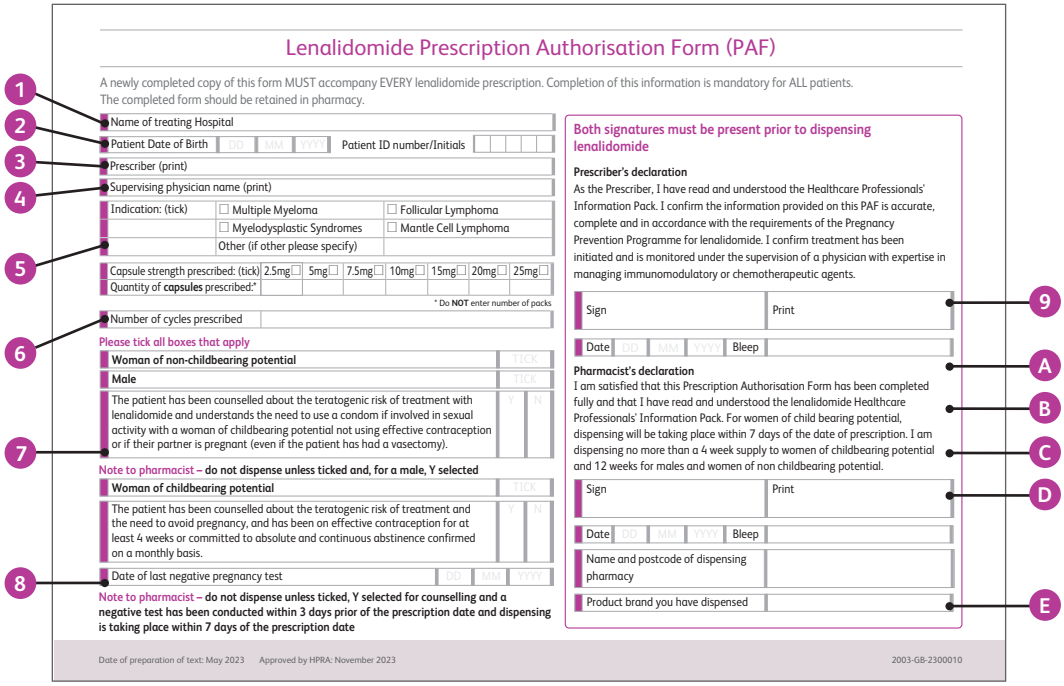


* Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.

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 complete the lenalidomide Prescription Authorisation Form (PAF). The form is used within the Pregnancy Prevention Programme and must be completed each time you prescribe lenalidomide.



Lenalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY lenalidomide 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 ☐ Follicular Lymphoma ☐ Myelodysplastic Syndromes ☐ Mantle Cell Lymphoma Other (if other please specify)

Capsule strength prescribed: (tick) 2.5mg☐ 5mg☐ 7.5mg☐ 10mg☐ 15mg☐ 20mg☐ 25mg☐
Quantity of **capsules** prescribed:*
* Do **NOT** enter number of packs

6 Number of cycles prescribed

Please tick all boxes that apply

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

8 Date of last negative pregnancy test DD MM YYYY

Note to pharmacist – **do not dispense unless ticked, Y 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 lenalidomide

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 lenalidomide. 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

Pharmacist's declaration
I am satisfied that this Prescription Authorisation Form has been completed fully and that I have read and understood the lenalidomide Healthcare Professionals' Information Pack. For women of child bearing 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 B C D Sign Print

Date DD MM YYYY Bleep

Name and postcode of dispensing pharmacy

E Product brand you have dispensed

Date of preparation of text: May 2023 Approved by HPRA: November 2023 2003-GB-2300010

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. Print your name clearly.
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. Print the indication for which lenalidomide is being prescribed – this is for the purposes of monitoring off-label use.
6. Enter the capsule strength, quantity of capsules prescribed and number of cycles prescribed.
7. Complete this section appropriately to indicate that counselling has occurred, 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 included lenalidomide 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

E. Record the brand of lenalidomide dispensed for each dispensing cycle the PAF was used for. This will assist in completion of the pharmacy self-audit for the particular lenalidomide brand.

10.0 Prescriber's Guide to Prescribing lenalidomide

In order to initiate therapy with lenalidomide:

1. Read the lenalidomide 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 Patient Pocket Information Card) to the patient.
   b. Obtain patient's signature for the Risk Awareness Form and provide patient with a copy.

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

For the FIRST prescription of lenalidomide

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 lenalidomide. Fax or email this form to the Nominated Community Pharmacy.
3. Prescribe lenalidomide 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 lenalidomide must be accompanied by a **'lenalidomide Prescription Authorisation Form'.**

For SUBSEQUENT prescriptions of lenalidomide

Follow steps 1 to 3

1. Prescribers wishing to prescribe must read and understand the Healthcare Professionals' Information Pack.
2. Prescribe lenalidomide 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 lenalidomide must be accompanied by a **'lenalidomide Prescription Authorisation Form'.**

11.0 Pharmacist's Guide to Dispensing Revlimid®

In order to dispense Revlimid®:

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 lenalidomide.

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.
2. Read and understand 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 **'Revlimid® Order Form'**.
5. Fax or email **'Revlimid® Order Form'** to UDD on 01 463 2404 or specialorders@united-drug.com. 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 **'Revlimid® Order Form'**.
2. Fax or email the **'Revlimid® Order Form'** to UDD on 01 463 2404 or specialorders@united-drug.com. UDD aim to deliver complete orders placed before 13:30 Monday - Friday for the following working day.

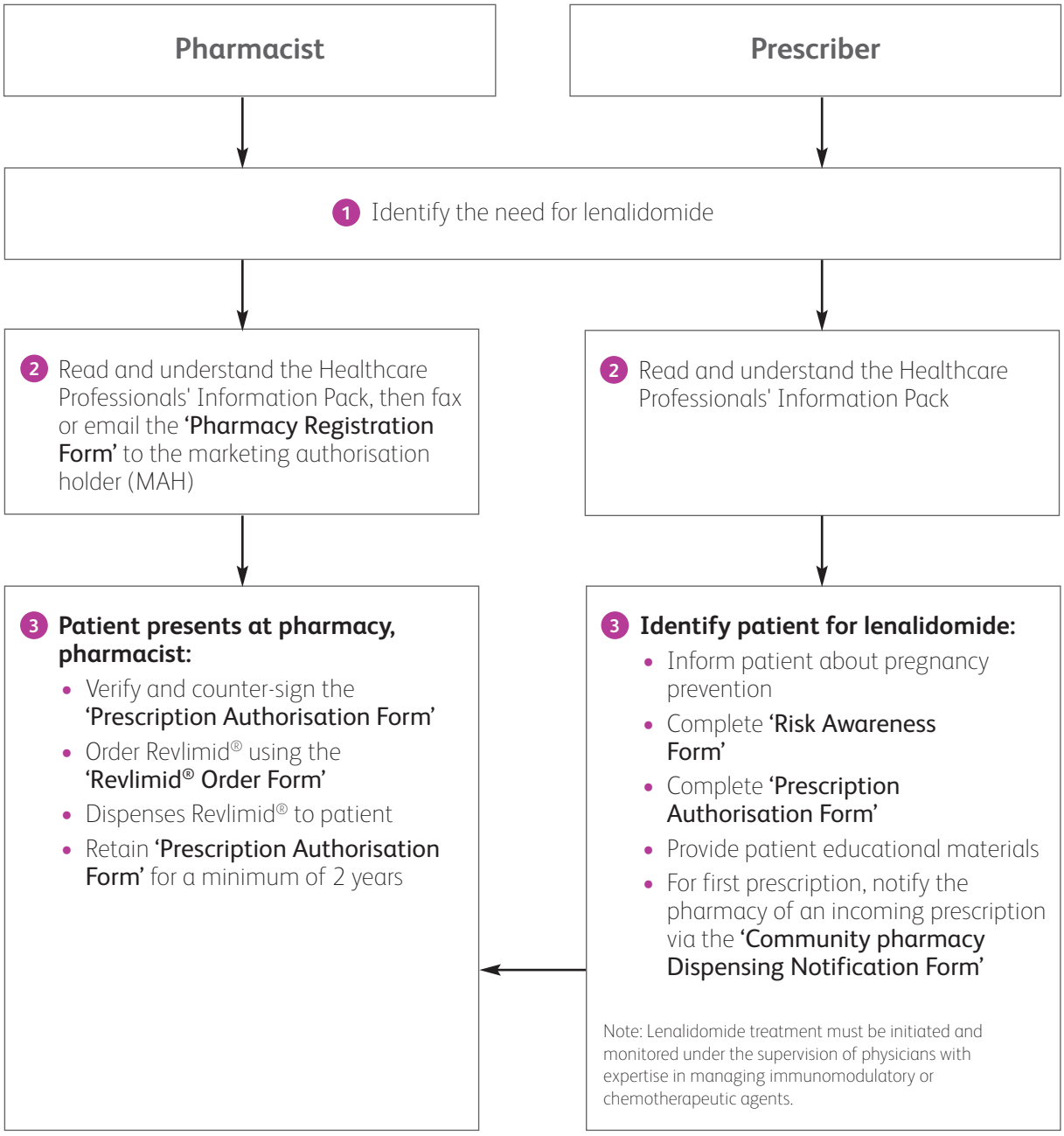
NB. Please ensure that all details are completed on this order form in full to ensure your order is processed appropriately and in a timely manner.

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

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

Dispense lenalidomide from High Technology Prescription.

12.0 Prescribing and Dispensing of lenalidomide 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 lenalidomide Healthcare Professionals' Information Pack or the patient materials?

If you would like further copies of the Revlimid® Healthcare Professionals' Information Pack or patient materials, please telephone or email Bristol-Myers Squibb (BMS) using the contact details below, or by speaking to any BMS representative. They can also be found on the following website: www.medicines.ie.

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

What are the maximum prescription lengths for treatment with lenalidomide?

The maximum prescription lengths for treatment with lenalidomide is 4 weeks for Women of Childbearing Potential patients and 12 weeks for Males and Women of Non-childbearing Potential patients.

What must I do prior to prescribing lenalidomide?

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

What must I do prior to ordering or dispensing Revlimid®?

All pharmacies must register with BMS prior to ordering or dispensing Revlimid®. You will need to register the dispensing pharmacy using the Revlimid® Pharmacy Registration Form. Completed Pharmacy Registration Forms should be sent via email (rmpukire@bms.com). Once you have returned a completed Pharmacy Registration Form, the pharmacy will be placed on the registered list and we will inform the distributor.

Where do I order Revlimid®?

Once registered, to order Revlimid® please contact our distributor – United Drug Distribution. You must have returned the Revlimid® Pharmacy Registration Form to BMS before you can place an order. You will need to complete the Revlimid® Order Form contained within the Healthcare Professionals' Information Pack and fax or email your order to the distributor.

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 pregnancies for a BMS product 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 for Medical Information, please telephone or Email the Medical Information department using the contact details below:

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

Queries and Adverse Event/pregnancy (suspected pregnancy) reports can be reported at: www.globalbmsmedinfo.com

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

The terms of the Revlimid® 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 Revlimid®.

BMS have agreed with the HPRA that pharmacies can fulfill 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 a Revlimid® Self-Audit pack, such that annual self-auditing of pharmacies and feedback of the Revlimid® 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.

14.0 Contact Details

This Healthcare Professional Information Guide is produced by BMS for Revlimid® (lenalidomide).

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

Data Protection:

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

Distributor for Revlimid®:

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™

Date of preparation of text: May 2023
Approved by HPRA: November 2023

Lenalidomide Pregnancy Prevention Programme Patient Guide

Information for patients taking lenalidomide

IRELAND

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed 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 for BMS products should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com

Date of preparation of text: May 2023
Approved by HPRA: November 2023

This guide contains information about:

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

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

This guide will help you understand what to do before, during and after taking lenalidomide.

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

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

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

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

Lenalidomide passes into men's semen, and is expected to cause severe birth defects or death to an unborn baby. So there is a risk if you have unprotected sex with a woman who can become pregnant.

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

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

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

Contents

Introduction

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

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

Your prescriber will discuss with you what condition lenalidomide treatment is being used for. You may also refer to the Package Leaflet that comes with your medicine for more detail on what lenalidomide is used for.

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

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

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

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

Lenalidomide and Birth Defects

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

- Women who are pregnant
- Women of childbearing potential, unless they follow the lenalidomide Pregnancy Prevention Programme

Lenalidomide and Other Possible Side Effects

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

Reporting of Side Effects
If you get any side effects, talk to your prescriber, pharmacist or nurse. This includes any possible side effects not listed in this guide. You can also report side effects directly via the HPRA Pharmacovigilance website: www.hpra.ie.

Special monitoring

Before and during the treatment with lenalidomide you will have regular blood tests. This is because lenalidomide may cause a fall in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets). Your prescriber will ask you to have a blood test:

- before treatment
- every week for the first 8 weeks of treatment
- then at least every month after that

Your prescriber will also monitor how well your kidneys are working.

Your prescriber may adjust your dose of lenalidomide or stop your treatment based on the results of your blood tests and on your general condition.

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

Pregnancy Prevention Programme

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

- Before starting lenalidomide 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.
- 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.
- In order to ensure that an unborn baby is not exposed to lenalidomide, 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 lenalidomide and for at least 4 weeks after stopping lenalidomide.
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity, you will have pregnancy tests under the supervision of your prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruptions and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation).
- If you are able to become pregnant, unless you commit to absolute and continuous abstinence confirmed on a monthly basis, you must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of the treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with lenalidomide. It is essential therefore that you discuss this with your prescriber. If necessary, your hospital team can refer you to a specialist for advice on contraception.

- **Do not take lenalidomide** if you are pregnant, think you may be pregnant or are planning to become pregnant, **as lenalidomide is expected to be harmful to an unborn child.**
- If you suspect you are pregnant at any time whilst taking lenalidomide or in the 4 weeks after stopping, you must stop lenalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

Childbearing Potential Assessment

Female patients will be assessed by their prescriber for childbearing potential, and unless you fall into one of the following categories you must follow the contraceptive advice presented in the next section:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during breastfeeding, then there is still a chance you could become pregnant).
- Your womb has been removed (hysterectomy).
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo-oophorectomy).
- You have premature ovarian failure, confirmed by a specialist gynaecologist.
- You have the XY genotype, Turner syndrome or uterine agenesis.

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

Women of Childbearing Potential

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a teratogenic effect is expected.

- **Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.**
- In order to ensure that an unborn baby is not exposed to lenalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 4 weeks after stopping lenalidomide.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.
- You must never take lenalidomide if:
  - You are pregnant.
  - You are a woman who is able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

- If you are a woman who could become pregnant you must either:
  - Use adequate contraception starting at least 4 weeks before lenalidomide treatment, during lenalidomide treatment, during any breaks in lenalidomide treatment and for at least 4 weeks after stopping lenalidomide treatment.

    OR

  - Agree you will not engage in sexual activity with a male partner starting at least 4 weeks before lenalidomide treatment, during lenalidomide treatment, during any breaks in lenalidomide treatment and for at least 4 weeks after stopping lenalidomide treatment. You will be asked to confirm this every month.
- Inform the prescriber of your contraception that you are on lenalidomide.
- Inform your prescriber of lenalidomide if you have changed or stopped the method of contraception.
- You should start your lenalidomide treatment as soon as possible after having a negative pregnancy test result and having received lenalidomide.
- Not all types of contraception are suitable during lenalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

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

Males

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a teratogenic effect is expected.

- **Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.**
- Ask your prescriber to inform you on which are the effective contraceptive methods that your female partner can use.
- In order to ensure that an unborn baby is not exposed to lenalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for your partner **NOT** to become pregnant throughout the duration of your treatment with lenalidomide and for at least 7 days after you stop lenalidomide.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood, semen or sperm during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- Lenalidomide passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use condoms throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop lenalidomide even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking lenalidomide or within 7 days after you have stopped taking lenalidomide, you should inform your prescriber immediately and your partner should also consult her doctor immediately.
- For additional information, please refer to the Package Leaflet.

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

Women of Non-Childbearing Potential

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a teratogenic effect is expected.

- Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.
- In order to ensure that an unborn baby is not exposed to lenalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become pregnant.
- You should never share lenalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.

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

Lenalidomide Treatment

Before Starting Your Treatment

Your prescriber will talk to you about what to expect from your treatment, and explain the risks and your responsibilities.

If there is anything you do not understand, please ask your prescriber to explain it again.

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

- 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.
- If you are able to become pregnant you will follow the necessary requirements to prevent pregnancy.
- You understand the other important safety messages.
- As a male patient, you understand the need to use condoms during treatment (including dose interruptions) and for at least 7 days after stopping lenalidomide if your partner is pregnant or is of childbearing potential and not using effective contraception.

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

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 or will be sent directly to your pharmacy each time you are prescribed lenalidomide. 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 lenalidomide.

For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply and you must have the medication dispensed within 7 days of the prescription date. A negative pregnancy test must also be confirmed on the prescription authorisation form before lenalidomide 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

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

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

What to do if you forget to take your lenalidomide:

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

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

Taking other medicines

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

How to Take Your Medication

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

- Your prescriber will prescribe a dose of lenalidomide suited to you.
- Always take lenalidomide exactly as 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.
- Lenalidomide capsules should be swallowed whole, with a glass of water.
- Lenalidomide can be taken at any time of day but it should be taken at approximately the same time each day.
- Lenalidomide can be taken with or without food.
- Do not break, open or chew the capsules. If powder from a broken lenalidomide capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.

End of Treatment Requirements

After completing your lenalidomide treatment, it is important that:

- You return any unused lenalidomide capsules to your pharmacist.
- You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

- Continue using your effective method of contraception for at least a further 4 weeks.
- Your prescriber will perform a final pregnancy test after at least 4 weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

- If you have been using an effective method of contraception, you must continue doing so for at least 7 days.
- If your female partner has been using an effective method of contraception, she must continue doing so for at least 4 weeks.
- Do not donate semen or sperm for at least 7 days.

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

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

Keep the blisters with the capsules in the original pack.

Care must be taken when removing capsules from the blister packaging to ensure that capsules are not broken. Please refer to the Package Leaflet that comes with your medicine for instructions on how to remove the capsule from the blister to reduce the risk of damage to the capsule. Please note the method of removal may differ depending on which lenalidomide product you are dispensed.

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.

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 the proper technique when removing gloves to prevent potential skin exposure (see over).
- 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 lenalidomide 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:

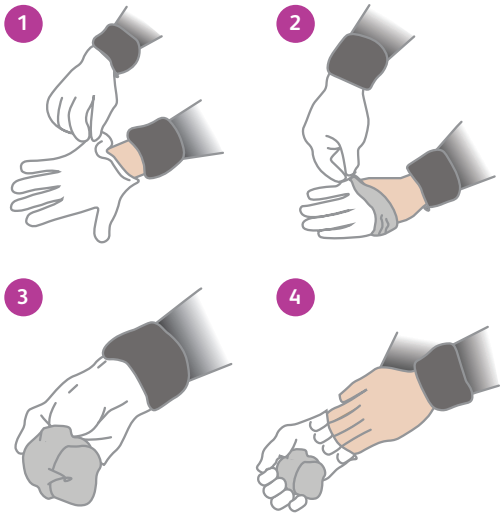
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of the powder into the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



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 when starting lenalidomide to confirm that you have understood all of the important information regarding your lenalidomide treatment.

All Patients

- ☐ Yes, I have understood that I should never share lenalidomide 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.
- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking lenalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking lenalidomide.
- ☐ 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.

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping lenalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
- ☐ 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 lenalidomide.

Female Patients who can become pregnant

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

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

Date of preparation of text: May 2023
Approved by HPRA: November 2023

Information for Patients and Healthcare Professionals:

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

- Women of childbearing potential must always use effective contraception.
- Women 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 lenalidomide, patients should read the Package Leaflet and HCPs should read the Summary of Product Characteristics.

Date of preparation of text: July 2023
Approved by HPRA: November 2023

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 lenalidomide for the treatment of:

Emergency Contact Information

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

Date of preparation of text: July 2023
Approved by HPRA: November 2023

Lenalidomide Pregnancy Prevention Programme (PPP)

Woman of Childbearing Potential Risk Awareness Form

IRELAND

Date of preparation of text: May 2023
Approved by HPRA: November 2023

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

This Risk Awareness Form is to assist you with counselling a patient before they commence lenalidomide 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 lenalidomide 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 lenalidomide. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of lenalidomide 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: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient'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 lenalidomide	*Tick*
3) Of the need to avoid lenalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment	*Tick*
4) That if she needs to change or stop using her method of contraception she should inform: a) the prescriber prescribing her contraception that she is taking lenalidomide b) the prescriber prescribing lenalidomide that she has stopped or changed her method of contraception	*Tick*
5) Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment	*Tick*
6) Of the need to stop lenalidomide immediately upon suspicion of pregnancy	*Tick*
7) Of the need to contact their prescriber immediately upon suspicion of pregnancy	*Tick*
8) To not share the medicinal product with any other person	*Tick*
9) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of lenalidomide	*Tick*
10) That they should return the unused capsules to the pharmacist at the end of treatment	*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 lenalidomide.	*Tick*
13) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	*Tick*
14) About which are effective contraceptive methods that she can use.	*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		YES	NO
Contraceptive consultation conducted on	DD	MM	YYYY

Pregnancy Prevention

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

Pregnancy Test

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

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND THE 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 lenalidomide, especially the risks to women of childbearing potential.

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

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 are expected to occur with the use of lenalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking lenalidomide.	*Patient initials*
I understand that I must not take lenalidomide if I am pregnant or plan to become pregnant.	*Patient initials*
I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in the case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	*Patient initials*
I understand that if I need to change or stop my method of contraception I will discuss this first with the healthcare professional prescribing my contraception and the prescriber prescribing my lenalidomide.	*Patient initials*
I understand that before starting the lenalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	*Patient initials*
I understand that I must immediately stop taking lenalidomide and inform my prescriber if I become pregnant while taking this drug; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	*Patient initials*
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the lenalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	*Patient initials*
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	*Patient initials*
I understand that even if I have amenorrhoea I must comply with advice on contraception.	*Patient initials*
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	*Patient initials*
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each lenalidomide 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 lenalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	*Patient initials*

Patient Confirmation

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

Your personal data is used solely for the purpose of entering you into the lenalidomide Pregnancy Prevention Programme and is processed by the marketing authorisation holder (MAH) of the lenalidomide product you receive, its third-party service providers and any affiliates the MAH may have, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes. Third party service providers include, for example, the distributor of the lenalidomide product you receive.

Your pharmacist can confirm the details of the MAH for the lenalidomide product you are given and this will also be mentioned on the packaging and package leaflet. Queries on how your personal data will be processed can be directed to the MAH in question, by consulting their publicly available information (e.g. on their website) which details how they process your personal data and provides a contact point for any queries in relation to their use of your personal data.

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 lenalidomide.

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

Bristol Myers Squibb™

Date of preparation of text: May 2023
Approved by HPRA: November 2023

Lenalidomide Pregnancy Prevention Programme (PPP)

Male Risk Awareness Form

IRELAND

Date of preparation of text: May 2023
Approved by HPRA: November 2023

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

This Risk Awareness Form is to assist you with counselling a patient before they commence lenalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each male prior to the initiation of their lenalidomide 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 lenalidomide. It is mandatory that male patients receive counselling and education to be made aware of the risks of lenalidomide.

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: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient'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 lenalidomide.	*Tick*
4) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
5) That lenalidomide 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*
6) That if his partner becomes pregnant, he should inform his treating prescriber immediately and always use a condom and his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	*Tick*
7) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of lenalidomide.	*Tick*
8) Of the hazards and necessary precautions associated with use of lenalidomide.	*Tick*
9) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	*Tick*
10) About the effective contraceptive methods that the female partner of a male patient can use.	*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 lenalidomide, especially the risks to women of childbearing potential.

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

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 are expected to occur with the use of lenalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking lenalidomide.	Patient initials
I understand that lenalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop lenalidomide even if I have had a vasectomy.	Patient initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I understand that I cannot donate blood while taking lenalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	Patient initials
I know that I cannot donate semen or sperm while taking lenalidomide, during dose interruptions and for at least 7 days after discontinuation of lenalidomide treatment.	Patient initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about which are effective contraceptive methods that my female partner can use.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	Patient initials
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each lenalidomide 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 lenalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	Patient initials

Patient Confirmation

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

Your personal data is used solely for the purpose of entering you into the lenalidomide Pregnancy Prevention Programme and is processed by the marketing authorisation holder (MAH) of the lenalidomide product you receive, its third-party service providers and any affiliates the MAH may have, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes. Third party service providers include, for example, the distributor of the lenalidomide product you receive.

Your pharmacist can confirm the details of the MAH for the lenalidomide product you are given and this will also be mentioned on the packaging and package leaflet. Queries on how your personal data will be processed can be directed to the MAH in question, by consulting their publicly available information (e.g. on their website) which details how they process your personal data and provides a contact point for any queries in relation to their use of your personal data.

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 lenalidomide.

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

Bristol Myers Squibb™

Date of preparation of text: May 2023
Approved by HPRA: November 2023

Lenalidomide Pregnancy Prevention Programme (PPP)

Woman of Non-Childbearing Potential Risk Awareness Form

IRELAND

Date of preparation of text: May 2023
Approved by HPRA: November 2023

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

This Risk Awareness Form is to assist you with counselling a patient before they commence lenalidomide 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 lenalidomide 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 lenalidomide. It is mandatory that woman of non-childbearing potential receive counselling and education to be made aware of the risks of lenalidomide.

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: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient'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 lenalidomide.	*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 lenalidomide.	*Tick*
5) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	*Tick*

Prescriber Confirmation

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

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

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 are expected to occur with the use of lenalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking lenalidomide.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	Patient initials
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each lenalidomide 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 lenalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	Patient initials

Patient Confirmation

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

Your personal data is used solely for the purpose of entering you into the lenalidomide Pregnancy Prevention Programme and is processed by the marketing authorisation holder (MAH) of the lenalidomide product you receive, its third-party service providers and any affiliates the MAH may have, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes. Third party service providers include, for example, the distributor of the lenalidomide product you receive.

Your pharmacist can confirm the details of the MAH for the lenalidomide product you are given and this will also be mentioned on the packaging and package leaflet. Queries on how your personal data will be processed can be directed to the MAH in question, by consulting their publicly available information (e.g. on their website) which details how they process your personal data and provides a contact point for any queries in relation to their use of your personal data.

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 lenalidomide.

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

Bristol Myers Squibb™

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Lenalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY lenalidomide 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	☐ Follicular Lymphoma	
	☐ Myelodysplastic Syndromes	☐ Mantle Cell Lymphoma	
	Other (if other please specify)		

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

* Do **NOT** enter number of packs

Number of cycles prescribed	

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 lenalidomide 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 and the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.	Y	N
Date of last negative pregnancy test	DD MM YYYY	

Note to pharmacist – do not dispense unless ticked, Y 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 lenalidomide

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 lenalidomide. 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	

Pharmacist's declaration

I am satisfied that this Prescription Authorisation Form has been completed fully and that I have read and understood the lenalidomide Healthcare Professionals' Information Pack. For women of child bearing 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			
Product brand you have dispensed			

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Lenalidomide 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 lenalidomide for your patient. This will enable the community pharmacy to register with the Lenalidomide Pregnancy Prevention Programme and subsequently be able to order and dispense lenalidomide for your patient.

Please complete the Prescriber section below upon the first occasion that the patient is being prescribed lenalidomide 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 lenalidomide for their patient. The patient has nominated your pharmacy to dispense the prescription.

All pharmacies dispensing lenalidomide must be registered with the Lenalidomide Pregnancy Prevention Programme for the product they intend to dispense. If you are not already registered, you must register now to order lenalidomide. Order Forms are available from the manufacturer.

If you choose to dispense Revlimid®▼, you must register with BMS using the Revlimid® Pharmacy Registration Form (if not already registered). Please contact BMS Risk Management on 1800 992 427 and BMS will forward you the required information.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

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Revlimid®▼ (lenalidomide) 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 lenalidomide as specified by Bristol-Myers Squibb (BMS) in the Revlimid® Healthcare Professionals' Information Pack.

1	I have read and understood the Revlimid® Healthcare Professionals' Information Pack.	TICK
2	All pharmacists who dispense Revlimid® will have read and understood the Revlimid® Healthcare Professionals' Information Pack.	TICK
3	If supplied with Revlimid®, 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 lenalidomide will be dispensed only if accompanied by a completed lenalidomide Prescription Authorisation Form.	TICK
5	The pharmacist dispensing Revlimid® will check each prescription and Prescription Authorisation Form for completeness and countersign the authorisation form prior to dispensing.	TICK
6	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	Revlimid® 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 of Revlimid® to women of childbearing potential should occur within 7 days of the prescription.	TICK
10	After dispensing, lenalidomide Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years.	TICK
11	Pharmacies must undertake the **mandatory** annual self-audit of the PAFs.	TICK
12	I will notify BMS of any change in contact details.	TICK

I understand that registration to obtain and supply Revlimid® will only be granted if I agree to items 1–12 described above as supply of Revlimid® without participation in the required risk minimisation for pregnancy prevention is contrary to the conditions of the marketing authorisation. Registration is valid for 2 years at which point I will confirm that we are continuing to follow the risk minimisation procedures by completing this form and sending to BMS.

Sign:				
Print:	Date:	DD	MM	YYYY

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

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

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Revlimid®▼ (lenalidomide) 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 United Drug routine 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 lenalidomide being prescribed

Date of prescription

Product Description	Strength	Quantity required
Lenalidomide Capsules	5mg	
Lenalidomide Capsules	10mg	
Lenalidomide Capsules	15mg	
Lenalidomide Capsules	20mg	
Lenalidomide Capsules	25mg	

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 lenalidomide will be dispensed in accordance with the risk minimisation procedures for lenalidomide, as specified by Bristol-Myers Squibb in the Revlimid® Healthcare Professionals' Information Pack.

I confirm that treatment lengths will be limited to a maximum of 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 child bearing potential dispensing will be within 7 days of the date of prescription

Sign

Date

Telephone

Print

FOR INTERNAL USE ONLY:

Sales Order:_____ Date: _____ Initials: _____

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

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