Imnovid®▼
(pomalidomide)

Healthcare Professionals' Information Pack

IRELAND

Important Safety Information:
Healthcare Professionals involved in the prescribing or dispensing of pomalidomide 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 pomalidomide 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 pomalidomide, 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 pomalidomide 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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Version 5.0

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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: April 2023
Approved by HPRA: November 2023

Contents

1.0 Introduction

This guide contains the information needed for prescribing and dispensing pomalidomide, 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 pomalidomide.

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 pomalidomide and that they have provided written confirmation on the Risk Awareness Form, before starting treatment.

Imnovid® Pregnancy Prevention Programme

Pomalidomide is an immunomodulating medicinal product.

If pomalidomide 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 pomalidomide. 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 pomalidomide 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 Imnovid® Summary of Product Characteristics (SmPC). This can be found on the following website: www.medicines.ie.

When pomalidomide 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 The Imnovid® Pregnancy Prevention Programme

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. Pomalidomide induced, in rats and rabbits, malformations similar to those described with thalidomide.

If Imnovid® (pomalidomide) is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met (please refer to sections 4.4 and 4.6 of the SmPC for further details). This programme is designed to make sure that unborn babies are not exposed to pomalidomide.

- It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood the information provided in the Healthcare Professionals' Information Pack before prescribing or dispensing pomalidomide for any patient.
- You must ensure that your patient fully understands what you have told them about pomalidomide 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).
- Patients should be capable of complying with the requirements of safe use and handling of pomalidomide.
- Patients must be provided with a copy of the Patient Guide, a copy of the Risk Awareness Form and the Patient Pocket Information Card. These materials remind patients of the key educational information regarding the requirements of the pregnancy prevention programme and some of the important risks of treatment outlined in the Healthcare Professional Information Guide.

The Healthcare Professionals' Information Pack are materials required to facilitate the Imnovid® Pregnancy Prevention Programme and additional copies can be obtained by using the contact details on the front of this guide. They are also available electronically on the website www.hpra.ie (enter 'Imnovid' under 'Find a medicine' and click 'EdM' under the 'documents' column) and www.medicines.ie.

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of Imnovid® will only be allowed from pharmacies registered with Bristol-Myers Squibb (BMS). BMS will not authorise supply of Imnovid® 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 pomalidomide must read and understand the pomalidomide Healthcare Professionals' Information Pack.
- All Pharmacies who dispense Imnovid® must agree to implement risk minimisation by registering with the BMS Pregnancy Prevention Programme.
- Every prescription for pomalidomide must be accompanied by a Prescription Authorisation Form, which must be completed by the prescriber and the pharmacist.

The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in section 8.0.

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 amenorrhoeic 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 patients 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 pomalidomide 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 pomalidomide, 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 pomalidomide therapy finished, and even in case of dose interruption **or**
– commit to absolute and continuous abstinence 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 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 pomalidomide 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 THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND THE PREGNANCY TEST IS NEGATIVE.

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and 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 severe neutropenia or severe thrombocytopenia.

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

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

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

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

- Stop treatment immediately.
- Refer the female patient to a physician specialised or experienced in dealing with teratology for advice and evaluation.
- Notify BMS immediately of all suspected pregnancies in female patients by contacting BMS Medical Information. Tel: 1800749749; 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.
- Please also complete the Pregnancy Reporting Form included in the Healthcare Professionals' Information Pack. BMS will wish to follow-up with you on the outcome of all pregnancies.
- Suspected pregnancies can also be reported to the Health Products Regulatory Authority (HPRA) via www.hpra.ie.

3.3 Men

- In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided.
- Inform your patient which are the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen during treatment. As a precaution, and taking into account special populations with potentially prolonged elimination time such as renal impairment, all male patients taking pomalidomide, including those who have had a vasectomy as seminal fluid may still contain pomalidomide 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 pomalidomide or within 7 days after he has stopped taking pomalidomide 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 pomalidomide.

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

- Refer the female partner to a physician specialised or experienced in dealing with teratology for advice and evaluation.
- Notify BMS immediately by contacting BMS Medical Information (Tel: 1800 749 749; Email: medical.information@bms.com). Please also complete the Pregnancy Reporting Form included in the Healthcare Professionals' Information Pack. 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 be reported via the HPRA Pharmacovigilance website: www.hpra.ie.

3.4 Advice for all Patients

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

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

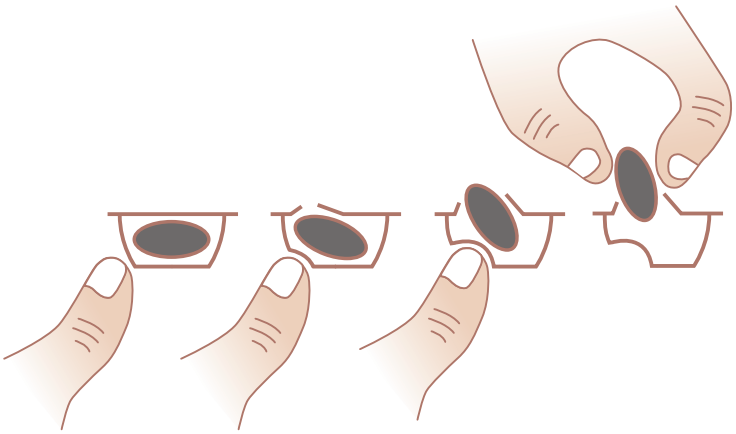
- Must not be shared with anyone else, even if they have similar symptoms.
- Must be stored away safely so no one else could take the capsules by accident.
- Must be kept out of reach and sight of children.

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

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

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

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local regulations. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



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

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see overleaf).
- Place gloves in a sealable plastic polyethylene bag and dispose of them according to local regulations.
- Wash hands thoroughly with soap and water after removing gloves.
- Do not give pomalidomide 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.

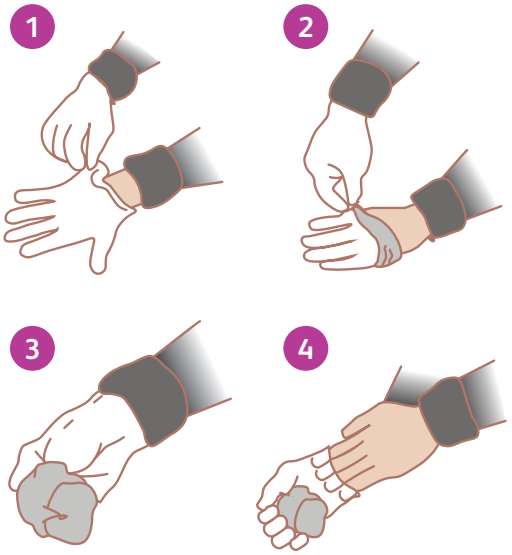
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air.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

Pomalidomide 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 pomalidomide 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 the appropriate contraceptive measures, if relevant.
- Perform a pregnancy test (if appropriate) before initiating treatment.

Community Pharmacy Notification

A pomalidomide 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 pomalidomide. The pomalidomide Community Pharmacy Dispensing Notification Form must be completed by the prescriber and faxed/emailed to the patients nominated pharmacy on the first occasion that the patient is being prescribed pomalidomide.

4.3 Subsequent Prescriptions

- **Before issuing subsequent prescriptions you must:**
  - Ensure your patient continues to understand the risks of pomalidomide therapy.
  - Ensure that your patient is continuing to use the appropriate contraceptive measures, if relevant.
  - Perform a pregnancy test, if relevant.
- Provide a 'Prescription Authorisation Form' to the patient with each pomalidomide prescription.

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

4.4 Prescription Authorisation Form

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

The prescriber must confirm on the prescription authorisation form:

- Patient initials, date of birth, and the indication for which pomalidomide is being prescribed.
- Name of the treating hospital, prescriber name, supervising physician name, signature and date.
- Confirmation that they have provided counselling on the teratogenic risk of pomalidomide and the required contraceptive measures for women of childbearing potential and male patients.
- Whether the patient is male, women 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.
- That the information provided on the Prescription Authorisation Form is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme for pomalidomide.
- That 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 pomalidomide. The patient must return to their prescriber for every repeat prescription of pomalidomide.

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 prescription.
- 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 Pomalidomide

Registration

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense Imnovid® 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.

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

In order to be registered, the Chief/Superintendent Pharmacist, or appointed deputy of the pharmacy wishing to dispense, must agree to implement and audit the use of a Prescription Authorisation Form. Your registration will remain valid for a period of 2 years, after which it must be renewed to continue dispensing this medication.

Ordering of pomalidomide

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

Community Pharmacy Dispensing

An Imnovid® 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 pomalidomide for your patient. The pharmacy will need to register with the Imnovid® Pregnancy Prevention Programme prior to being able to order pomalidomide for your patient and dispense it. If the nominated pharmacy is not already authorised to supply Imnovid®, it must first contact BMS to register with them using the Imnovid® Pharmacy Registration Form. BMS will then send the pharmacy the relevant documentation if not already received.

There must be a valid Prescription Authorisation Form for each dispensing of pomalidomide.

4.6 Dispensing Advice

For women of childbearing potential:

- The date of the last pregnancy test, must be within the 3 days prior to the date of the prescription.
- Dispensing of pomalidomide 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 pomalidomide 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 pomalidomide 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 pomalidomide blisters intact. Capsules must not be removed from blisters and packaged into bottles.
- Instruct patients to return any unused pomalidomide to the pharmacy. Pharmacies must accept any unused pomalidomide 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 dispensing procedures for pomalidomide.

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

The terms of the Imnovid® Marketing Authorisation require 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 in patients to pomalidomide as well as monitor off-label use.

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

BMS will supply pharmacies with an audit pack, such that annual self-auditing of pharmacies and feedback of the audit results to BMS can occur.

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

6.0 Other Selected Risks of Imnovid®

The following section contains advice to Healthcare Professionals about how to minimise the risk of thrombocytopenia and cardiac failure associated with the use of pomalidomide. Please refer also to the SmPC (see Sections 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects) for complete information on all the risks associated with pomalidomide.

In general, most adverse reactions occurred more frequently during the first 2 to 3 months of treatment. Please note that the posology, adverse event profile and recommendations outlined herein, particularly in respect of thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication. For further information about the appropriate use and safety profile of pomalidomide, please refer to the SmPC.

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

6.1 Risk of thrombocytopenia and cardiac failure with pomalidomide

6.1.1 Thrombocytopenia

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide. It is therefore encouraged to monitor complete blood counts (CBC) - including platelet count - weekly for the first 8 weeks and monthly thereafter. A dose modification or interruption may be required. Patients may require use of blood product support and /or growth factors. Thrombocytopenia can be managed with dose modifications and/or interruptions. Recommended dose modifications during treatment and restart of treatment with pomalidomide are outlined in the table below:

Dose Modification or Interruption Instructions

Toxicity	Dose Modification
Thrombocytopenia • Platelet Count <25 x 10^9/L • Platelet Count return to ≥50 x 10^9/L	Interrupt pomalidomide treatment, follow CBC weekly Resume pomalidomide treatment at one dose lower than previous dose
• For each subsequent drop <25 x 10^9/L • Platelet count return to ≥50 x 10^9/L	Interrupt pomalidomide treatment Resume pomalidomide treatment at one dose level lower than the previous dose

CBC – Complete Blood Count

To initiate a new cycle of pomalidomide, the platelet count must be ≥50 x 10^9/L.

6.1.2 Cardiac Failure

Cardiac events, including congestive cardiac failure, pulmonary oedema and atrial fibrillation (see Section 4.8 of the SmPC), have been reported, mainly in patients with pre-existing cardiac disease or cardiac risk factors. Appropriate caution should be exercised when considering the treatment of such patients with pomalidomide, including periodic monitoring for signs or symptoms of cardiac events (see Section 4.4 of the SmPC).

6.2 Blood Donation

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

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

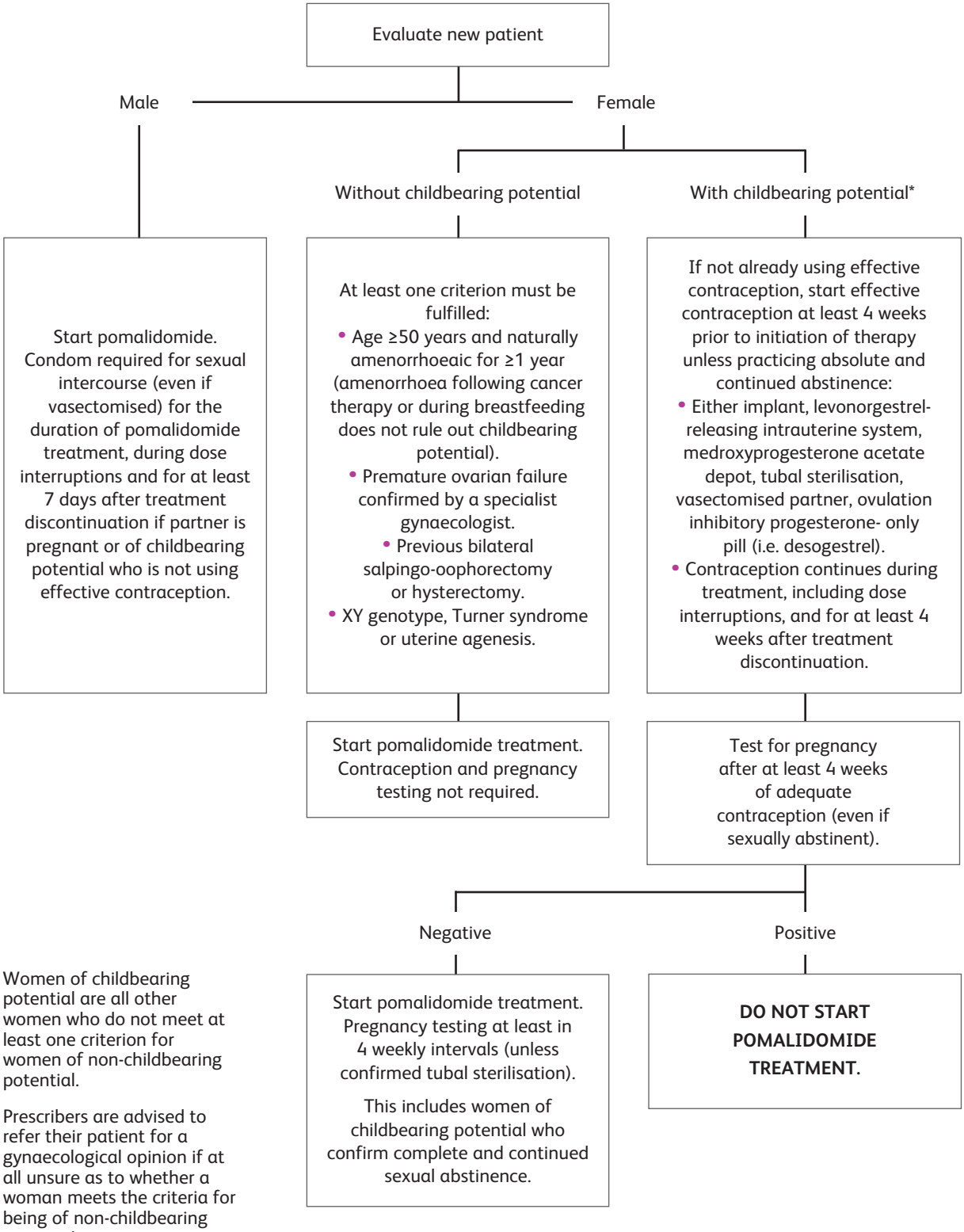
The safe use of pomalidomide is of paramount importance.

As part of BMS's ongoing safety monitoring, the company wishes to learn of Adverse Events that have occurred during the use of pomalidomide. Adverse Events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported to the HPRA via the HPRA Pharmacovigilance website www.hpra.ie and also to BMS medical information. For any pregnancy reports the Pregnancy Reporting Forms available as part of the Healthcare Professionals' Information Pack should be completed and forwarded to BMS Medical Information.

Email: medical.information@bms.com

Tel: 1800 749 749

8.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm

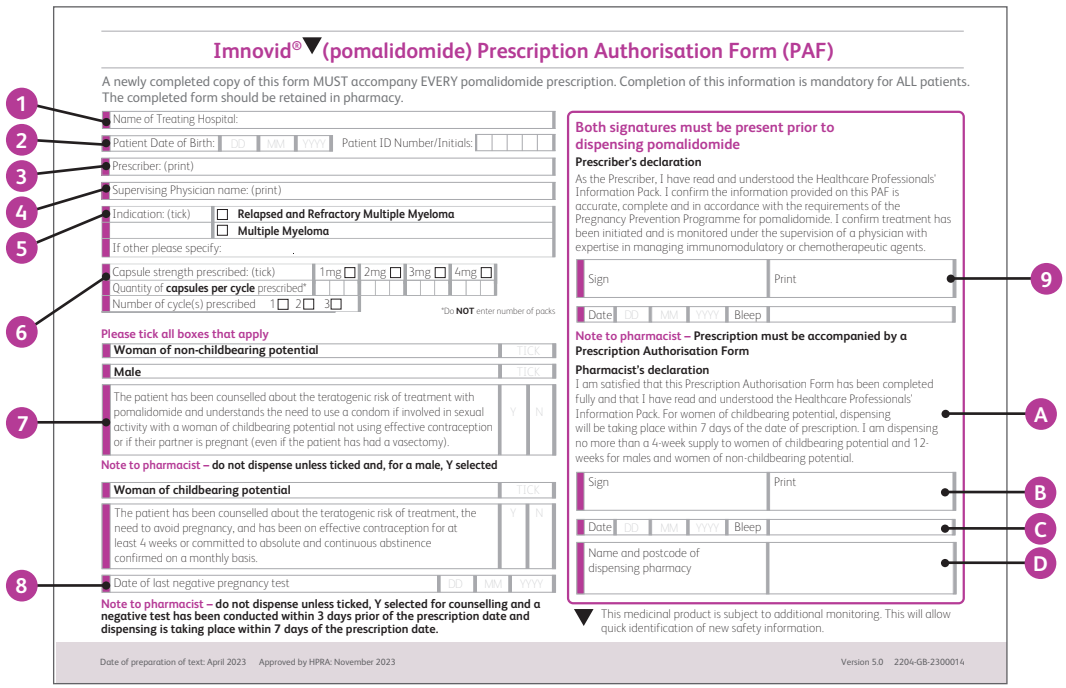


* Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.

Prescribers are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

9.0 How to Complete the Prescription Authorisation Form

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



Imnovid®▼(pomalidomide) Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY pomalidomide 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) ☐ **Relapsed and Refractory Multiple Myeloma** ☐ **Multiple Myeloma**

If other please specify:

6 Capsule strength prescribed: (tick) 1mg ☐ 2mg ☐ 3mg ☐ 4mg ☐

Quantity of **capsules per cycle** prescribed*

Number of cycle(s) prescribed 1☐ 2☐ 3☐

*Do **NOT** enter number of packs

Please tick all boxes that apply

Woman of non-childbearing potential TICK

Male TICK

7 The patient has been counselled about the teratogenic risk of treatment with pomalidomide and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy). Y N

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

Woman of childbearing potential TICK

The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective 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 pomalidomide

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 pomalidomide. 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 9

Date DD MM YYYY Bleep

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

Pharmacist's declaration

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

Sign Print B

Date DD MM YYYY Bleep C

Name and postcode of dispensing pharmacy D

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

Date of preparation of text: April 2023 Approved by HPRA: November 2023 Version 5.0 2204-GB-2300014

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. Tick the indication box or state other usage – 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 and appropriate contraceptive measures are in place. This is a requirement of the Pregnancy Prevention Programme.
8. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescribing). If this is not the case pomalidomide must not be dispensed.
9. You must sign, date and print your name to declare that all steps have been observed and that you authorise the Prescription Authorisation Form.

Instructions for pharmacists

A. Check that all relevant sections of the form have been fully completed by the prescriber including:
   a. That counselling and contraceptive measures have been confirmed by the prescriber as appropriate.
   b. That for woman of childbearing potential a negative pregnancy test date is provided within 3 days of the prescription date.
   c. The indication, capsule strength, capsule quantity and number of cycles have been provided.

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

C. Check the form is complete and legible.

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

Further information and materials are available from BMS.

Tel: 1800 992 427

Email: rmpukire@bms.com

10.0 Prescriber's Guide to Prescribing Imnovid®

In order to initiate therapy with pomalidomide:

1. Read the Imnovid® Healthcare Professionals' Information Pack.
2. Evaluate childbearing potential of patient and implement the Pregnancy Prevention Programme as required.
3. Evaluate risks relevant to all patients, take relevant precautions and provide counselling as appropriate.
   a. Provide educational materials (Patient Guide and a Patient Pocket Information Card) to the patient.
   b. Obtain patient's signature for Risk Awareness Form and provide the patient with a copy.

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

For the FIRST prescription of Imnovid®

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

For SUBSEQUENT prescriptions of Imnovid®

Follow steps 1 to 3

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

11.0 Pharmacist's Guide to Dispensing Imnovid®

In order to dispense pomalidomide:

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 pomalidomide.

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

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

You are a Pharmacy that has previously registered with BMS

Complete an **'Imnovid® Order Form'.**

1. Fax the **'Imnovid® Order Form'**
2. to UDD on 01 463 2404. UDD aim to deliver complete orders placed before 13:30 Monday - Friday for the following working day.

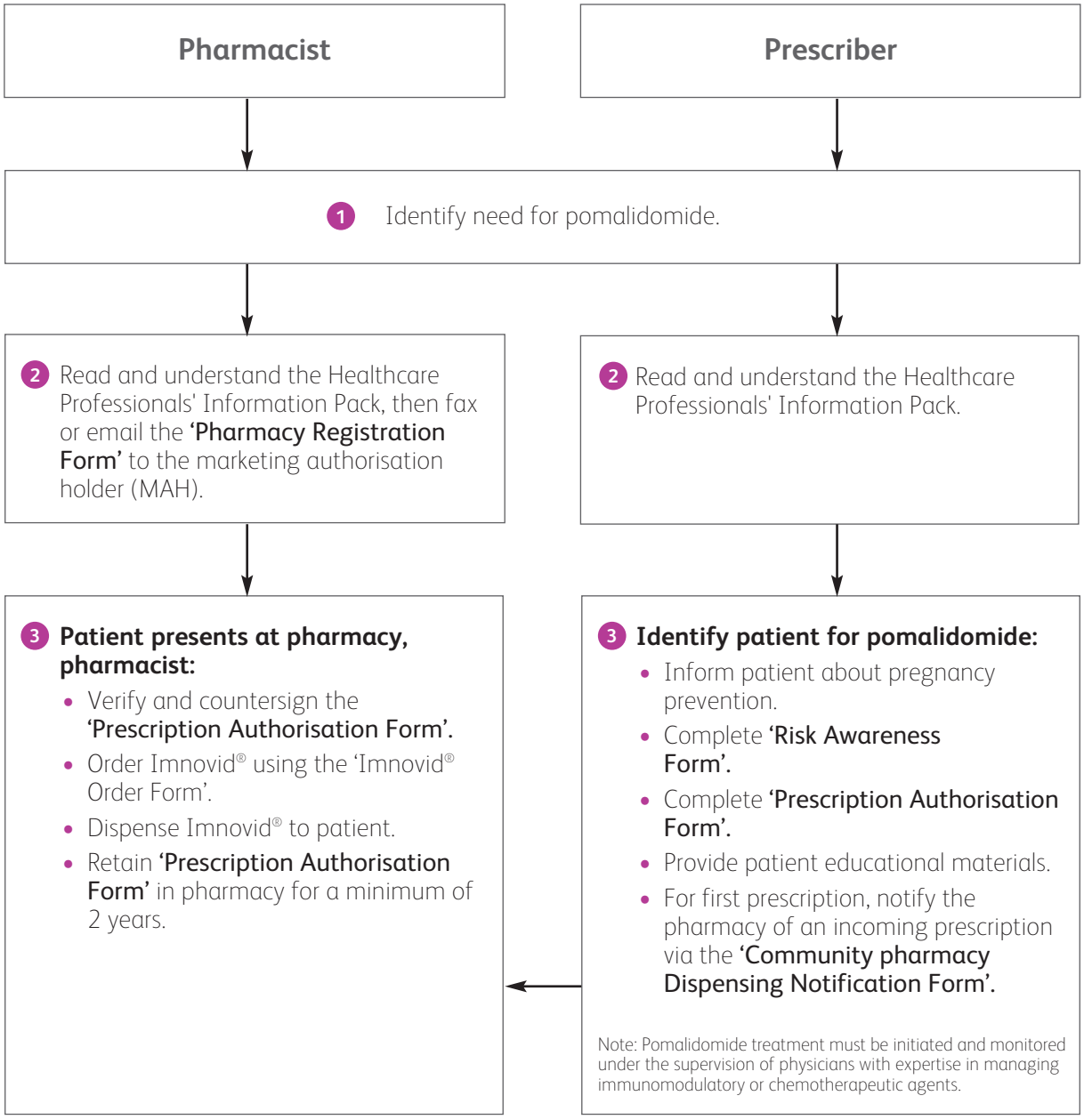
NB. Please ensure that all details are completed on this order form in full to ensure your order is processed appropriately and in a timely manner.

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

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

Dispense pomalidomide from High Technology Prescription.

12.0 Prescribing and Dispensing Imnovid® 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 Imnovid®▼(pomalidomide) Healthcare Professionals' Information Pack or the patient materials?

If you would like further copies of the Imnovid® Healthcare Professionals' Information Pack or any other materials for healthcare professionals or patients, please telephone or email Bristol-Myers Squibb (BMS) using the contact details below. These materials are also available electronically at www.medicines.ie or www.hpra.ie.

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

What are the maximum prescription durations for each different patient category?

The maximum prescription duration for a Woman of Childbearing Potential is 4-weeks. The maximum prescription duration for a Male patient and a Woman of Non-Childbearing Potential is 12-weeks.

What must I do prior to ordering or dispensing pomalidomide?

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

Do I need a registration number to order pomalidomide?

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

Where do I order pomalidomide?

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

Distributor: United Drug Distribution (UDD)
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 should be reported to BMS Medical Information using the contact details below (using the BMS Pregnancy Reporting Form available in Healthcare Professionals' Information Pack or electronically at www.medicines.ie).

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

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

To contact BMS 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 reports can be reported at: www.globalbmsmedinfo.com

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

The terms of the Imnovid® 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 pomalidomide.

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

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

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

14.0 Contact Details

Risk Management:

For information and questions on the Risk Management of BMS products, the Pregnancy Prevention Programme, pharmacy registrations and the use of the Prescription Authorisation Form.

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

Medical Information:

To report any Adverse Events or suspected pregnancies, or to obtain Medical Information on BMS products.

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

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

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

Data Protection:

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

Distributor for Imnovid®:

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: April 2023
Approved by HPRA: November 2023

Imnovid®▼(pomalidomide) Pregnancy Prevention Programme Patient Guide

Information for patients taking pomalidomide

IRELAND
Version 5.0

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

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.

Risk Management contact details:
Tel: 1800 992 427
Fax: 1800 992 429
Email: rmpukire@bms.com

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

This guide contains information about:

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

Imnovid® Pregnancy Prevention Programme: This programme is designed to make sure that unborn babies are not exposed to pomalidomide. 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 pomalidomide.

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

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

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

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

Pomalidomide 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 the Package Leaflet and this guide 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 pomalidomide capsules.

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

Contents

Introduction

Imnovid® is the trade name for pomalidomide and it is used to treat adults with a type of cancer called 'multiple myeloma'. Pomalidomide works in a number of different ways:

- by stopping the cancer cells developing.
- by stimulating the immune system to attack the cancer cells.
- by stopping the formation of blood vessels supplying the cancer cells.

Pomalidomide is either used with:

- two other medicines - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

Or

- one other medicine - called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

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

Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans. Therefore precautions must be taken to avoid exposure to pomalidomide in an unborn baby.

This guide is part of the "Imnovid® Pregnancy Prevention Programme", which is necessary because if pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

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

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

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

Pomalidomide and Birth Defects

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

- Women who are pregnant.
- Women who could become pregnant, unless they follow the Imnovid® Pregnancy Prevention Programme.

Pomalidomide and Other Possible Side Effects

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

Before and during the treatment with pomalidomide you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your prescriber should ask you to have a blood test:

- before treatment.
- every week for the first 8 weeks of treatment.
- at least every month after that for as long as you are taking pomalidomide.

As a result of these tests, your prescriber may change your dose of pomalidomide or stop your treatment. The prescriber may also change the dose or stop the medicine because of your general health.

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

- Before starting pomalidomide 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 pomalidomide, 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 pomalidomide and for at least 4 weeks after stopping pomalidomide.
- 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 interruption 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 your 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 pomalidomide. 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 pomalidomide** if you are pregnant, think you may be pregnant or are planning to become pregnant, as **pomalidomide is expected to be harmful to an unborn child.**
- If you suspect you are pregnant at any time whilst taking pomalidomide or in the 4 weeks after stopping treatment, you must stop pomalidomide 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

Before starting pomalidomide 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.

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

Pomalidomide is expected to be harmful to the unborn child.

- **Pomalidomide 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 pomalidomide, 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 pomalidomide and for at least 4 weeks after stopping pomalidomide.
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result.
- You should never share pomalidomide 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 pomalidomide 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.
- You must stop treatment and inform your doctor straight away if you have heterosexual intercourse without using an effective method of contraception.

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

Contraception to Prevent Pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment.

or

- Agree you will not engage in sexual activity with a male partner starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment. You will be asked to confirm this every month.

Inform the prescriber of your contraception that you are on pomalidomide.

Inform your prescriber of pomalidomide if you have changed or stopped the method of contraception.

You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result.

Not all types of contraception are suitable during pomalidomide 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.

Males

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

- **Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.**
- Pomalidomide 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 pomalidomide even if you have had a vasectomy.
- 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 pomalidomide, 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 pomalidomide and for at least 7 days after you stop pomalidomide.
- You should never share pomalidomide 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.
- If your partner does become pregnant whilst you are taking pomalidomide or within 7 days after you have stopped taking pomalidomide, 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 pomalidomide you should tell your prescriber or pharmacist.

Women of Non-Childbearing Potential

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

- Pomalidomide 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 pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become pregnant.
- You should never share pomalidomide 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 pomalidomide you should tell your prescriber or pharmacist.

Pomalidomide 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 pomalidomide:

- You understand the risks of birth defects and the actions you must take to prevent this risk from occurring depending on whether you are a female patient who can become pregnant, a male patient or a female patient who cannot become pregnant.
- If you are able to become pregnant you will follow the necessary requirements to prevent pregnancy.
- You understand the other important safety messages.
- As a male patient you understand the need to use condoms during treatment (including dose interruptions) and for at least 7 days after stopping pomalidomide 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. 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 pomalidomide.

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 pomalidomide 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

You must never take pomalidomide if you are allergic to pomalidomide or to any of the other ingredients contained in the capsule.

You should never share pomalidomide 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.

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

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

If you forget to take your dose of pomalidomide on one day, then take the normal prescribed dose as scheduled on the next day. You should not adjust the dose to make up for a missing dose on previous days.

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

For additional information please refer to the Package Leaflet.

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

How to store pomalidomide safely

- Keep your pomalidomide in a safe place out of the reach and sight of children.
- Keep your pomalidomide capsules in the original box at room temperature.
- Do not use after the expiry date written on the box.

End of Treatment Requirements

After completing your pomalidomide treatment, it is important that:

- You return any unused pomalidomide 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 contraceptive method, you must continue doing so for at least 7 days.
- If your female partner has been using an effective contraceptive method, she must continue doing so for at least 4 weeks.
- Do not donate semen or sperm for at least 7 days.

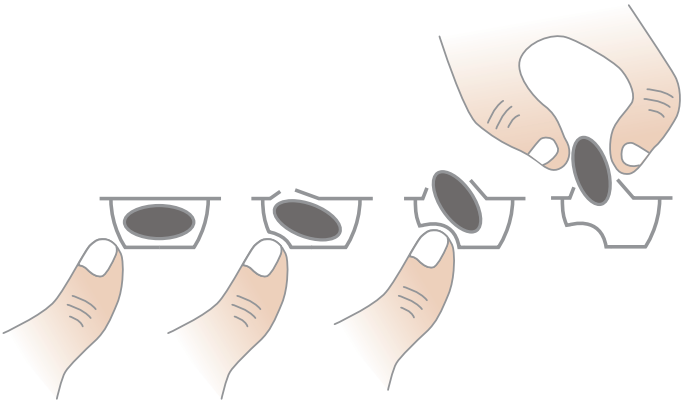
Points to Consider for Handling the Medicinal Product: For Patients, Family Members and Caregivers

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.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

Healthcare professionals, family members, and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local regulations. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



When Handling the Medicinal Product Use the Following Precautions to Prevent Potential Exposure if you are a Family Member and/or Caregiver:

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and or packaging (i.e., blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see next page).
- Place gloves in a sealable plastic polyethylene bag and dispose them according to local regulations.
- Wash hands thoroughly with soap and water after removing gloves.
- Do not give pomalidomide to another person.

If a Drug Product Package Appears Visibly Damaged, Use the Following Extra Precautions to Prevent Exposure:

- If the 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:

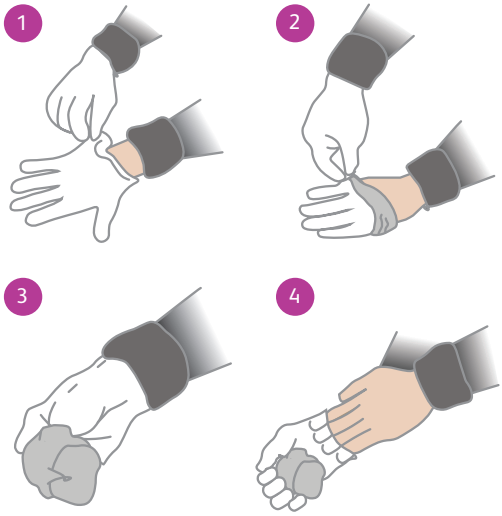
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. 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 regulations for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the prescriber and/or pharmacist immediately.

If the Contents of the Capsule are Attached to the Skin or Mucous Membranes:

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap.
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist.

Proper Technique for Removing Gloves:

- Grasp outside edge near wrist (1).
- Peel away from hand, turning glove inside-out (2).
- Hold in opposite gloved hand (3).
- Slide ungloved finger under the wrist of the remaining glove, 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 check list to confirm that you have understood all of the important information regarding your pomalidomide treatment.

All Patients

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

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping pomalidomide, 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 pomalidomide.

Female Patients who can become pregnant

- ☐ Yes, I will use one effective method of contraception for at least 4 weeks before starting pomalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped pomalidomide treatment.
- ☐ Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every 4 weeks during treatment and at least 4 weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

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

This Patient Guide is produced by BMS.

Medical Information:

To report any Adverse Events or suspected pregnancies, or to obtain Medical Information on BMS products.

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

Data Protection:

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

Bristol Myers Squibb™

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

Information for Patients and Healthcare Professionals:

Imnovid® ▼ (pomalidomide) 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 pomalidomide, patients should read the Package Leaflet and HCPs should read the Summary of Product Characteristics.

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Approved by HPRA: November 2023
Version 5.0

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 pomalidomide for the treatment of:

Emergency Contact Information:

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

Further information is available in the Patient guide.

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

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Imnovid®▼(pomalidomide) Pregnancy Prevention Programme

Woman of Childbearing Potential Risk Awareness Form

IRELAND

Version 5.0

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

Date of preparation of text: April 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 POMALIDOMIDE

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female prior to the initiation of their pomalidomide 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 pomalidomide. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of pomalidomide 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: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. 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 pomalidomide 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 Imnovid®.	Tick
3) Of the effective contraception she can use.	Tick
4) Of the need to avoid Imnovid® during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment.	Tick
5) That if she needs to change or stop using her method of contraception she should inform: a) the prescriber prescribing her contraception that she is taking Imnovid®. b) the prescriber prescribing Imnovid® that she has stopped or changed her method of contraception.	Tick
6) Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment.	Tick
7) Of the need to stop Imnovid® immediately upon suspicion of pregnancy.	Tick
8) Of the need to contact their prescriber immediately upon suspicion of pregnancy.	Tick
9) To not share the medicinal product with any other person.	Tick
10) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®.	Tick
11) That even if patient has amenorrhoea they must comply with advice on contraception.	Tick
12) Of hazards and necessary precautions associated with use of Imnovid®.	Tick
13) That they should return the unused capsules to the pharmacist at the end of treatment.	Tick
14) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Imnovid®.	Tick

Can you confirm your patient:

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

Contraceptive Referral

Contraceptive referral made on	DD	MM	YYYY
Contraceptive consultation conducted on	DD	MM	YYYY

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	Tick
Levonorgestrel-releasing intrauterine system (IUS)	Tick
Medroxyprogesterone acetate depot	Tick
Tubal sterilisation	Tick
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	Tick
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	Tick
Committed to 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 overleaf the nature, purpose and risks of treatment associated with pomalidomide, especially the risks to women of childbearing potential.
I will comply with all my obligations and responsibilities as the prescriber of pomalidomide.

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 may occur with the use of pomalidomide. 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 pomalidomide.	*Patient initials*
I understand that I must not take pomalidomide 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 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 method and the prescriber prescribing my pomalidomide.	*Patient initials*
I understand that before starting pomalidomide 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 pomalidomide 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 pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the Imnovid® Patient Guide and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	*Patient initials*
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused pomalidomide 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 pomalidomide.	*Patient initials*
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each pomalidomide 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 pomalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of pomalidomide.	*Patient initials*

Patient Confirmation

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

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

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

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

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

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	*DD*	*MM*	*YYYY*

Bristol Myers Squibb™

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

Imnovid®▼(pomalidomide) Pregnancy Prevention Programme

Woman of Non-Childbearing Potential Risk Awareness Form

IRELAND

Version 5.0

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

Date of preparation of text: April 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 POMALIDOMIDE.

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

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: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. 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 pomalidomide 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 Imnovid®.	*Tick*
3) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
4) Of hazards and necessary precautions associated with use of Imnovid®.	*Tick*
5) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Imnovid®.	*Tick*

Prescriber Confirmation

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

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

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 may occur with the use of pomalidomide. 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 pomalidomide.	Patient initials
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the Imnovid® Patient Guide and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	Patient initials
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused pomalidomide 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 pomalidomide.	Patient initials
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each pomalidomide 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 pomalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of pomalidomide.	Patient initials

Patient Confirmation

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

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

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

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

Patient Signature:		Date:	DD	MM	YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	DD	MM	YYYY

Bristol Myers Squibb™

Date of preparation of text: April 2023
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Imnovid®▼(pomalidomide) Pregnancy Prevention Programme

Male Risk Awareness Form

IRELAND

Version 5.0

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

Date of preparation of text: April 2023
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RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF POMALIDOMIDE.

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

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: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. 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 pomalidomide 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 Imnovid®.	*Tick*
4) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
5) Of the effective contraceptive measures he or his female partner can use.	*Tick*
6) That Imnovid® is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy) throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment.	*Tick*
7) That if his partner becomes pregnant, he should inform his treating prescriber immediately, his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	*Tick*
8) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®.	*Tick*
9) Of hazards and necessary precautions associated with use of Imnovid®.	*Tick*
10) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Imnovid®.	*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 overleaf the nature, purpose and risks of treatment associated with pomalidomide, especially the risks to women of childbearing potential.

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

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 may occur with the use of pomalidomide. 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 pomalidomide.	Patient initials
I have been told by my prescriber that I must NEVER have unprotected sexual contact with women who are pregnant or may become pregnant, whilst I am taking pomalidomide and for at least 7 days after stopping treatment.	Patient initials
I understand that pomalidomide 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 pomalidomide even if I have had a vasectomy.	Patient initials
I understand that if my partner does become pregnant whilst I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide I should inform my prescriber immediately and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the Imnovid® Patient Guide and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	Patient initials
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I know that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after discontinuation of pomalidomide.	Patient initials
I understand that I must return any unused pomalidomide 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 pomalidomide.	Patient initials
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each pomalidomide 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 pomalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of pomalidomide.	Patient initials

Patient Confirmation

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

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

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

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

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

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	*DD*	*MM*	*YYYY*

Bristol Myers Squibb™

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

Imnovid® ▼ (pomalidomide) Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY pomalidomide 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)	☐ **Relapsed and Refractory Multiple Myeloma**
	☐ **Multiple Myeloma**
If other please specify:	

Capsule strength prescribed: (tick)	1mg ☐	2mg ☐	3mg ☐	4mg ☐
Quantity of **capsules per cycle** prescribed*				
Number of cycle(s) prescribed 1☐ 2☐ 3☐				

*Do **NOT** enter number of packs

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 pomalidomide and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).	Y	N

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

Woman of childbearing potential	TICK	
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective 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 pomalidomide

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 pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician with expertise in managing immunomodulatory or chemotherapeutic agents.

Sign	Print
Date DD MM YYYY Bleep	

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

Pharmacist's declaration

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

Sign	Print
Date DD MM YYYY Bleep	
Name and postcode of dispensing pharmacy	

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

Imnovid® ▼ (pomalidomide) 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 pomalidomide for your patient. This will enable the community pharmacy to register with Bristol-Myers Squibb (BMS) and subsequently be able to order and dispense pomalidomide for your patient.

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

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

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

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

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

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Imnovid®▼(pomalidomide) 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 pomalidomide as specified by BMS in the Imnovid® Healthcare Professionals' Information Pack.

1	I have read and understood the Imnovid® Healthcare Professionals' Information Pack.	TICK
2	All pharmacists who dispense Imnovid® will have read and understood the Imnovid® Healthcare Professionals' Information Pack.	TICK
3	If supplied with Imnovid®, 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 Imnovid® will be dispensed only if accompanied by a completed Imnovid® Prescription Authorisation Form.	TICK
5	The pharmacist dispensing Imnovid® 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	Imnovid® 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 Imnovid® to women of childbearing potential should occur within 7 days of the prescription.	TICK
10	After dispensing, Imnovid® 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 Imnovid® Prescription Authorisation Forms.	TICK
12	I will notify BMS of any change in contact details.	TICK

I understand that registration to obtain and supply Imnovid® will only be granted if I agree to items 1–12 described above as supply of Imnovid® 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 form 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.

Imnovid®▼(pomalidomide) 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 pomalidomide being prescribed

Date of prescription

Product Description	Strength	Quantity required
Pomalidomide Capsules	1mg	
Pomalidomide Capsules	2mg	
Pomalidomide Capsules	3mg	
Pomalidomide Capsules	4mg	
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 pomalidomide will be dispensed in accordance with the risk minimisation procedures for pomalidomide, as specified by Bristol-Myers Squibb in the Imnovid® Healthcare Professionals' Information Pack.

I confirm that treatment lengths will be limited to 4 weeks supply for Women of Childbearing Potential and 12 weeks for Males and Women of Non-childbearing Potential. For Women of Childbearing potential dispensing will be take place within 7 days of the date of prescription

Sign

Date

Telephone

Print

FOR INTERNAL USE ONLY:

Sales Order:_____ Date: _____ Initials: _____

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Version 5.0

IRELAND
Version 5.0

Imnovid®▼ (pomalidomide)
Pregnancy Report Form

Pregnancy reports must be sent to Bristol-Myers Squibb (BMS) Medical Information IMMEDIATELY
This form must be returned to BMS Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

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

Date of awareness: D D M O N Y Y Y Y

Patient Data

Sex of Patient: ○ Female ○ Male

○ Pregnancy of Patient
○ Pregnancy of Patient's Partner **OR**
○ Exposure of a Pregnant Female (complete information below)

Pregnant Woman's Initials (F, M, L): | Date of Birth: D D M O N Y Y Y Y | Age:

Patient Initials (F, M, L): (Who received drug) | Date of Birth: D D M O N Y Y Y Y | Age:

Drug Name:

Date of First Dose: D D M O N Y Y Y Y | Date of Last Dose: D D M O N Y Y Y Y

Pregnancy Initially Diagnosed By:

○ Home Urine Test
○ Office Urine Test
○ Serum Test

Date of Pregnancy Test: D D M O N Y Y Y Y | Last Menstrual Period: D D M O N Y Y Y Y

Female is Currently: ____ weeks pregnant **OR** ○ No longer Pregnant ○ Unknown

Female has Elected to: ○ Carry Pregnancy to Term | Expected Date of Delivery: D D M O N Y Y Y Y
○ Terminate Pregnancy | Date Performed or Pending: D D M O N Y Y Y Y

Reporter's Information:

Reporter's Name:	Date: D D M O N Y Y Y Y
Reporter's Contact Information/ Address:	Reporter's Signature:
	Reporter's Phone Number:
Reporter's Email Address:	Reporter's Fax Number:

Patient's Prescriber's Information:

Prescriber's Name:	Date: D D M O N Y Y Y Y
Prescriber's Contact Information/ Address:	Prescriber's Signature:
	Prescriber's Phone Number:
Prescriber's Email Address:	Prescriber's Fax Number:

Pregnancy reports must be sent to BMS Medical Information IMMEDIATELY

This form must be returned to BMS Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

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

Background Information on Reason for Pregnancy

Was patient erroneously considered not to be of childbearing potential?	○ Yes	○ No
If yes, state reason for considering not to be of childbearing potential		
• Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year. *amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential.	○ Yes	○ No
• Premature ovarian failure confirmed by a specialist gynaecologist.	○ Yes	○ No
• Previous bilateral salpingo-oophorectomy, or hysterectomy.	○ Yes	○ No
• XY genotype, Turner syndrome, uterine agenesis.	○ Yes	○ No
Indicate from the list below what contraception was used		
• Implant	○ Yes	○ No
• Levonorgestrel-releasing intrauterine system (IUS)	○ Yes	○ No
• Medroxyprogesterone acetate depot	○ Yes	○ No
• Tubal sterilisation (specify below)	○ Yes	○ No
○ Tubal ligation	○ Yes	○ No
○ Tubal diathermy	○ Yes	○ No
○ Tubal chips	○ Yes	○ No
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses.	○ Yes	○ No
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	○ Yes	○ No
• Other progesterone-only pills	○ Yes	○ No
• Combined oral contraceptive pill	○ Yes	○ No
• Other intra-uterine devices	○ Yes	○ No
• Condoms	○ Yes	○ No
• Cervical cap	○ Yes	○ No
• Sponge	○ Yes	○ No
• Withdrawal	○ Yes	○ No
• Other	○ Yes	○ No
• None	○ Yes	○ No
Indicate from the list below the reason for contraceptive failure		
• Missed oral contraception.	○ Yes	○ No
• Other medication or intercurrent illness interacting with oral contraception.	○ Yes	○ No
• Identified mishap with barrier method.	○ Yes	○ No
• Unknown	○ Yes	○ No
• Had the patient committed to complete and continuous abstinence.	○ Yes	○ No
• Was the drug started despite patient already being pregnant.	○ Yes	○ No
• Did patient receive educational materials on the potential risk of teratogenicity.	○ Yes	○ No
• Did patient receive instructions on need to avoid pregnancy.	○ Yes	○ No

Pregnancy reports must be sent to BMS Medical Information IMMEDIATELY

This form must be returned to BMS Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

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

Background Information on Reason for Pregnancy

Prenatal information

Date of Last Menstrual Period: D D M O N Y Y Y Y

Estimated Delivery Date: D D M O N Y Y Y Y

Pregnancy test

Urine Qualitative ◯	Reference Range:		Date: D D M O N Y Y Y Y
Serum Quantitative ◯	Reference Range:		Date: D D M O N Y Y Y Y

Past Obstetric History

Year of Pregnancy	Outcome				Gestational Age	Type of Delivery
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		
Y Y Y Y	◯ Spontaneous abortion	◯ Therapeutic abortion	◯ Live birth	◯ Still birth		

Birth defects

Was there any birth defect from any pregnancy?	◯ Yes	◯ No	◯ Unknown
Is there any family history of any congenital abnormality abstinence?	◯ Yes	◯ No	◯ Unknown

If yes to either of these questions, please provide details below:

Maternal Past Medical History

Condition	Dates	Treatment	Outcome
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		
	From: D D M O N Y Y Y Y To: D D M O N Y Y Y Y		

Pregnancy reports must be sent to BMS Medical Information IMMEDIATELY
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NOTE: Please use the first three letters of the month (e.g. JAN)

Maternal Current Medical Conditions

Condition	From	Treatment
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	
	D D M O N Y Y Y Y	

Maternal Social History

Alcohol ◯ Yes ◯ No
If yes, amount/units per day:

Tobacco ◯ Yes ◯ No
If yes, amount per day:

IV or recreational drug use ◯ Yes ◯ No
If yes, provide details:

Maternal medication during pregnancy and in 4 weeks before pregnancy

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Dates		Indication
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	
	Start Date:	D D M O N Y Y Y Y	
	Stop Date/Continuing:	D D M O N Y Y Y Y	

Name of person completing this form

Name:

Date: D D M O N Y Y Y Y

Signature:

Pregnancy reports must be sent to BMS Medical Information IMMEDIATELY

This form must be returned to BMS Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

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

Data Privacy Notice

Your personal data will be processed by Bristol-Myers Squibb Pharma EEIG (hereinafter "BMS"), for the purposes of complying with its drug safety legal obligations and for storage purposes.

BMS may share your data with other BMS entities and third parties providing services to BMS. This may entail the transfer of your data to other countries such as the USA and India. When such countries do not provide an equivalent level of protection to personal data as your country, BMS will implement appropriate legal, organisational, and technical security measures to protect your information from unauthorised access, use or disclosure, including the use of standard data protection clauses and Binding Corporate Rules. BMS will retain your personal data for the length of time required by law.

You have the right to access and verify your personal information held by BMS, receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing.

For the exercise of your rights and for any questions regarding data protection you can contact our Data Protection Officer: eudpo@bms.com. If you are unhappy about how BMS is processing your personal data, you have the right to lodge a complaint with the supervisory authority.

Reporter's Signature (required):

Signature:	Date signed: D D M O N Y Y Y Y

On behalf of BMS, thank you for providing information that will assist us in our commitment to patient safety.

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

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Imnovid®▼ (pomalidomide)

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

This form must be returned to Bristol-Myers Squibb (BMS) Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

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

Reporter information

Reporter Name:	
Address:	
City, County, Country:	
Phone No.:	
Fax No.:	

Patient information

Patient ID: ____ Date of Birth: D D M O N Y Y Y Y Ethnicity: ○ White ○ African-Caribbean ○ Other, specify below: ____

Partner of patient information

○ Not applicable Ethnicity: ○ White ○ African-Caribbean ○ Other, specify below: ____

Pregnancy outcome

Date of delivery: D D M O N Y Y Y Y Gestation age at delivery: ____

Normal	○ No	○ Yes
C-section	○ No	○ Yes
Induced	○ No	○ Yes
Ectopic pregnancy	○ No	○ Yes
Elective termination	○ No	○ Yes
Spontaneous abortion (≤20 weeks)	○ No	○ Yes
Foetal death/stillbirth (>20 weeks)	○ No	○ Yes
Were the products of conception examined?	○ No	○ Yes

Date: D D M O N Y Y Y Y
Weeks from LMP: ____

If yes, was the foetus normal? ○ No ○ Yes ○ Unknown If no, describe below: ____

Obstetrics information

Complications during pregnancy	○ No	○ Yes	If yes, please specify ____
Complications during labour/delivery	○ No	○ Yes	If yes, please specify ____
Post-partum maternal complications	○ No	○ Yes	If yes, please specify ____

Foetal outcome

Live normal infant	○ No	○ Yes	
Foetal distress	○ No	○ Yes	
Intra-uterine growth retardation	○ No	○ Yes	
Neonatal complication	○ No	○ Yes	If yes, please specify ____
Birth defect noted?	○ No	○ Yes	If yes, please specify ____

Sex: ○ Male ○ Female **Birth weight:** ____ lbs ____ oz. or ____ kg **Length:** ____ inches or ____ cm.

Apgar score: 1 min: ____ 5 min: ____ 10 min: ____ ○ Unknown

Signature of person completing this form

Signature: ____ Date: D D M O N Y Y Y Y

This form must be returned to BMS Medical Information
Tel: 1800 749 749 - Email: medical.information@bms.com

Drug Safety Data Privacy notice

Your personal data will be processed by Bristol-Myers Squibb Pharma EEIG (hereinafter "BMS"), for the purposes of complying with its drug safety legal obligations and for storage purposes.

BMS may share your data with other BMS entities and third parties providing services to BMS. This may entail the transfer of your data to other countries such as the USA and India. When such countries do not provide an equivalent level of protection to personal data as your country, BMS will implement appropriate legal, organisational, and technical security measures to protect your information from unauthorised access, use or disclosure, including the use of standard data protection clauses and Binding Corporate Rules. BMS will retain your personal data for the length of time required by law.

You have the right to access and verify your personal information held by BMS, receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing.

For the exercise of your rights and for any questions regarding data protection you can contact our Data Protection Officer: eudpo@bms.com. If you are unhappy about how BMS is processing your personal data, you have the right to lodge a complaint with the supervisory authority.

Reporter's Signature (required):

Signature:	Date signed: D D M O N Y Y Y Y

On behalf of BMS, thank you for providing information that will assist us in our commitment to patient safety.

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

Bristol Myers Squibb™