Imnovid®▼
(pomalidomide)

Healthcare Professional Information Guide

IRELAND

Version 5.0

▼ 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

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

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Contents

1.0 Introduction

This guide 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:

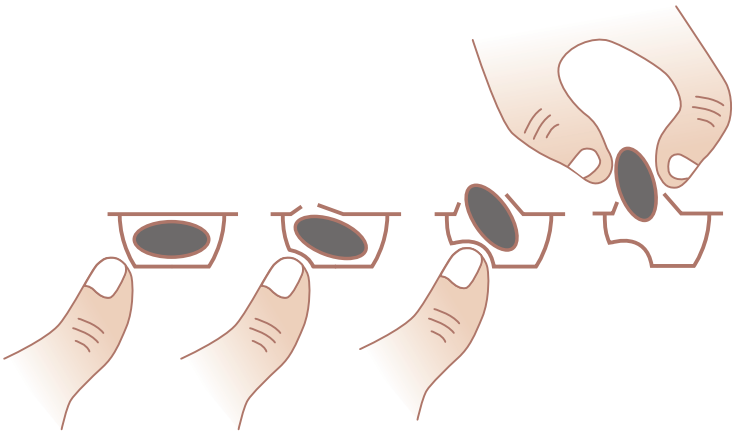
- Must not be shared with anyone else, even if they have similar symptoms.
- Must be stored away safely so no one else could take the capsules by accident.
- Must be kept out of reach and sight of children.

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.

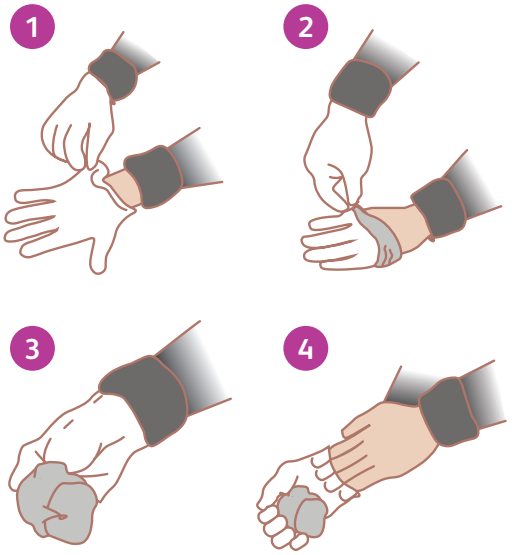
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air.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

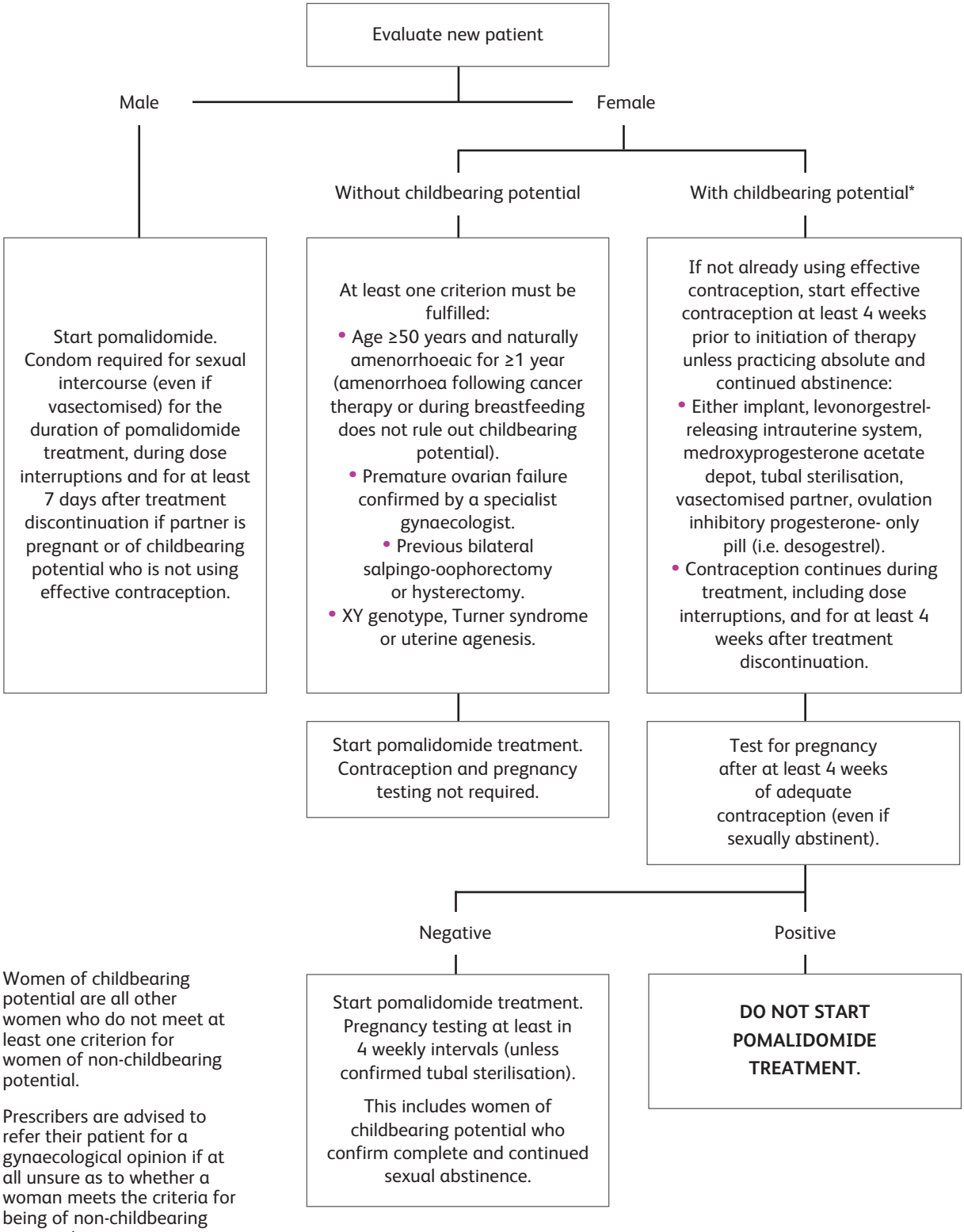
The safe use of pomalidomide is of paramount importance.

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

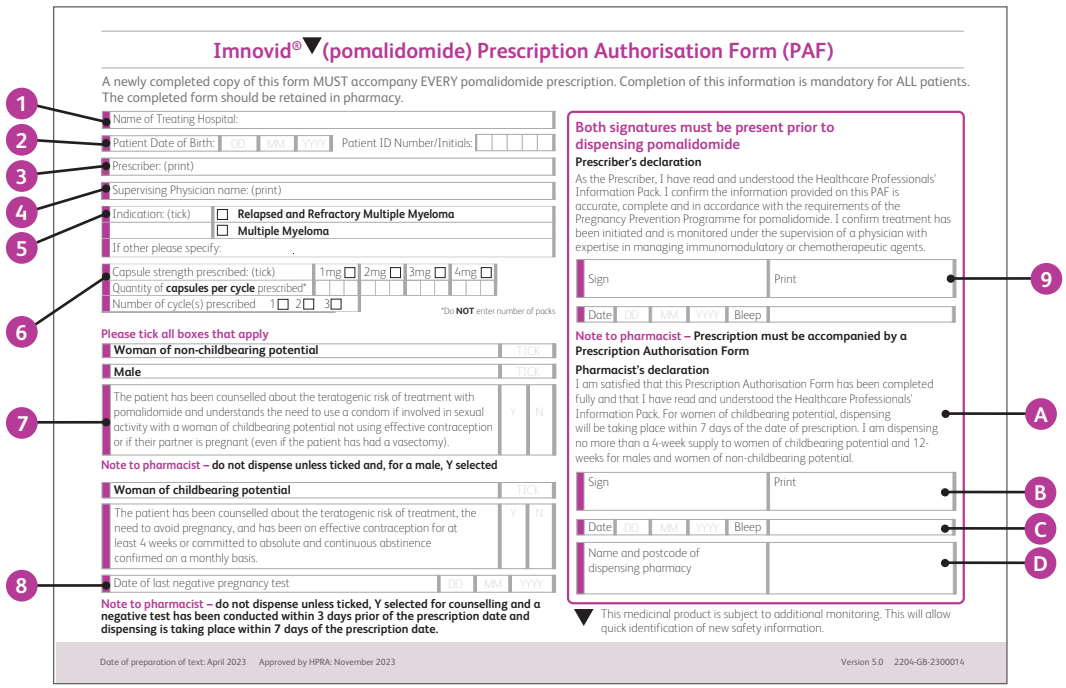


* Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential.

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.

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Instructions for prescribers

1. Print the full hospital name where the patient is treated.
2. Print the patient's date of birth and initials. If the middle initial is not known please use an underscore (e.g. J_S for John Smith). Do not provide confidential information (e.g. Patient Name and Hospital Number).
3. 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.

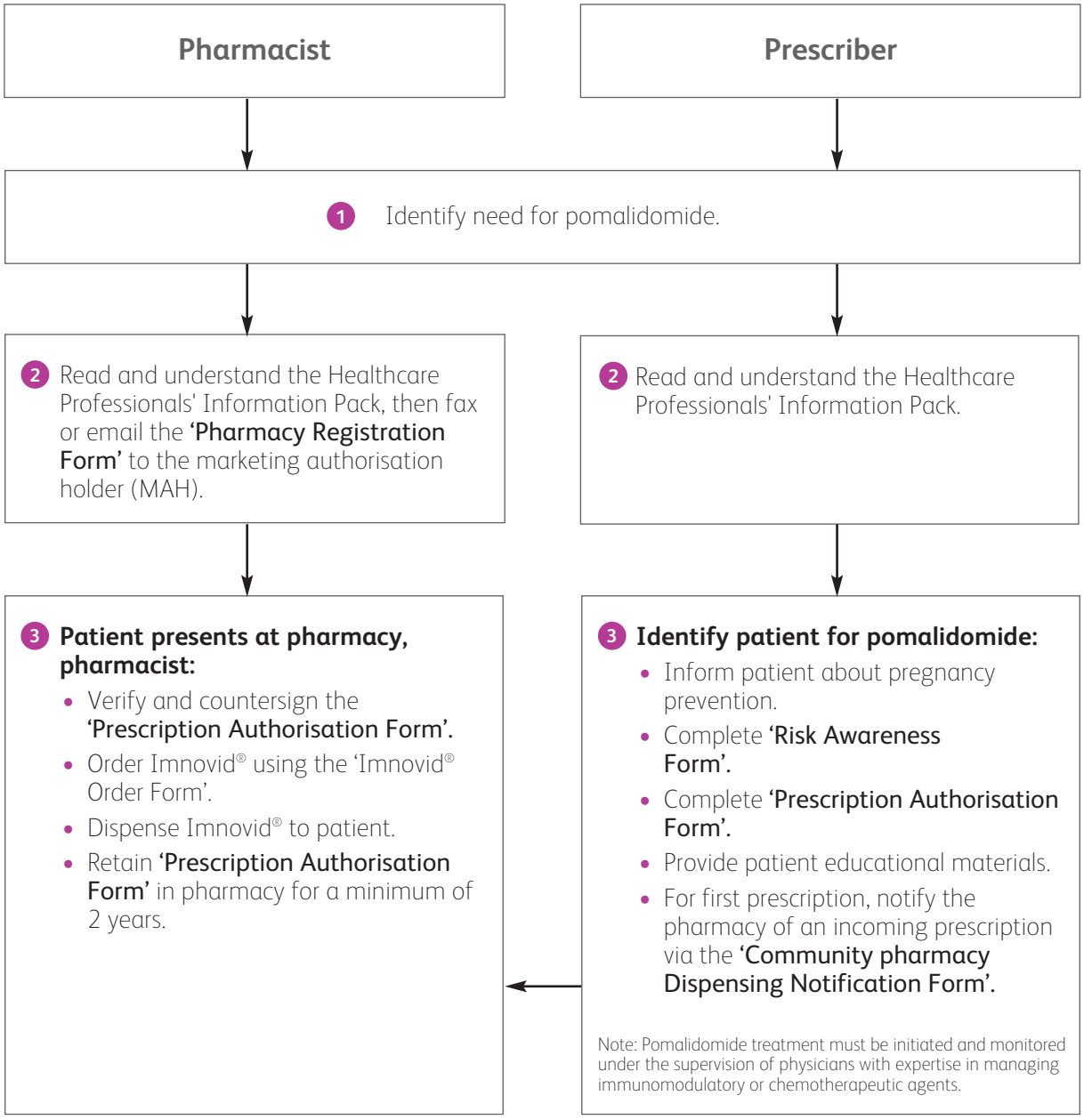
NB. Please ensure that all details are completed on this order form in full to ensure your order is processed appropriately and in a timely manner.

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™

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