Pomalidomide ▼
Pregnancy Prevention Programme

Information for Healthcare Professionals Prescribing or Dispensing Pomalidomide

Version 2.0

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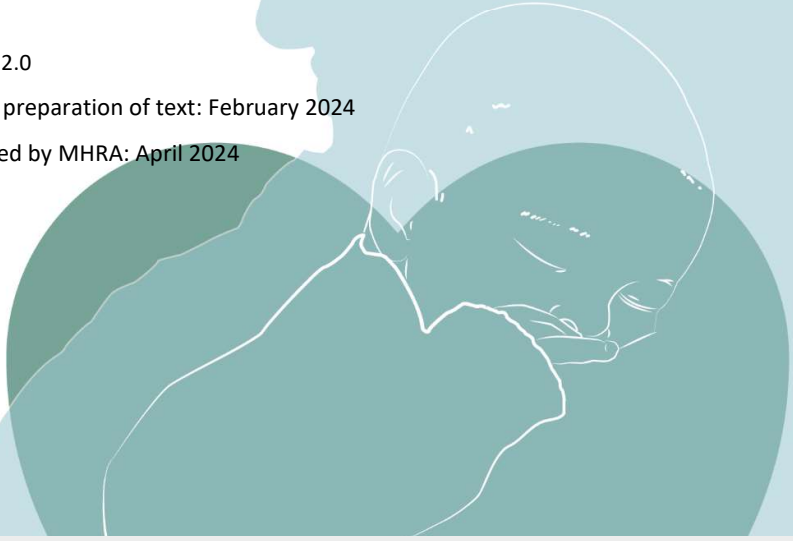


▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to the relevant MAH, using the contact details available within the Pathfinder PPP Platform.

This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the Pregnancy Prevention Programme (PPP). Please also refer to the Great Britain (GB) or Northern Ireland (NI) Summary of Product Characteristics (SmPC), which can be found on the GB or NI emc websites: www.medicines.org.uk/emc (for Great Britain) or https://www.emcmedicines.com/en-GB/northernireland (for Northern Ireland), for further information.

Pomalidomide Pregnancy Prevention Programme:

If pomalidomide is taken during pregnancy, it can 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.

Other side effects of Pomalidomide:

A full list of all side effects, further information and recommended precautions can be found in your Marketing Authorisation Holder's (MAH's) SmPC.

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

This brochure will help you understand these problems and make sure you know what to do before prescribing and dispensing pomalidomide.

For your patients' health and safety, please read this brochure 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 Assessment Form, before starting treatment.

Contents

1. Introduction

This brochure contains the information needed for prescribing and dispensing pomalidomide including information about the Pregnancy Prevention Programme (PPP).

For full details, please refer to the SmPC, which can be found on the emc website: www.medicines.org.uk/emc (for Great Britain) or https://www.emcmedicines.com/en-GB/northernireland/ (for Northern Ireland).

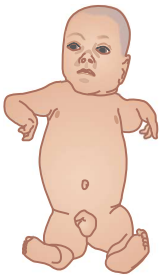
When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

1.1. Summary of the Pregnancy Prevention Programme

This brochure contains the information needed for the prescribing and dispensing of pomalidomide including information about the Pregnancy Prevention Programme.

Pomalidomide is structurally related to thalidomide, 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 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).



- 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 for counselling).
- 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 Brochure and Patient Pocket Information Card.
- In order to obtain pomalidomide, it is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood the Additional Risk Minimisation Materials before prescribing or dispensing pomalidomide for any patient.
- Prescribers must complete the appropriate Risk Awareness Form with every patient before the first prescription is issued.
- Pharmacies must register with pomalidomide Pregnancy Prevention Programme to be able to order and dispense pomalidomide. To do this, the pharmacist must contact PharmaCare Group Ltd. using the details at the end of this brochure.
- Every prescription for pomalidomide must be accompanied by a Prescription Authorisation Form (PAF) which can be completed electronically via the Pathfinder PPP platform by the prescriber and the pharmacist.
- Alternatively, in case of a temporary system unavailability, an off-line version of the PAF is available upon request, which must be sent immediately to PharmaCare Group Ltd (support@pharmacaregroup.co.uk).

All patients should be given a Patient Brochure and Patient Pocket Information Card to take home – these materials remind patients of the key educational information and risks of treatment and can be found in the Information for Patients page of the Pathfinder platform.

For women of childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription. Pharmacists are required to send copies of every PAF immediately after dispensing either via the Pathfinder PPP platform or, in case of a temporary system unavailability, an off-line copy to PharmaCare Group Ltd. (support@pharmacaregroup.co.uk)

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of pomalidomide will only be allowed from pharmacies registered with the Pathfinder PPP. The MAHs will not authorise supply of pomalidomide to pharmacies that are not registered. For pharmacies utilising a third-party pharmacy to dispense the product to the patient, both the pharmacy completing and approving the PAF and the dispensing pharmacy are required to be registered with the pomalidomide Pregnancy Prevention Programme.

The following are core requirements of the Pregnancy Prevention Programme:

- All healthcare professionals dispensing or prescribing pomalidomide must read the pomalidomide Pregnancy Prevention Programme materials.
- All pharmacies who dispense pomalidomide must agree to implement risk minimisation by registering with the Pathfinder Pregnancy Prevention Programme platform.
- If a third-party pharmacy is only dispensing pomalidomide, the pharmacy completing and approving the PAFs must also register with the Pathfinder Pregnancy Prevention Programme platform.
- Every prescription for pomalidomide must be accompanied by a PAF, which can be completed electronically via the Pathfinder PPP platform by the prescriber and the pharmacist.

1.2. Overview of the pomalidomide PPP materials

All pomalidomide Pregnancy Prevention Programme materials are contained within the Pathfinder PPP Platform as individual materials. Hard copies can be obtained by contacting the relevant MAH, using the contact details available within the Pathfinder PPP Platform or on the Great Britain (GB) and Northern Ireland (NI) electronic medicines compendium websites: www.medicines.org.uk/emc (for Great Britain) or www.emcmedicines.com/en-GB/northernireland (for Northern Ireland). You must ensure that your patients fully understand what you have told them about pomalidomide before starting treatment.

This brochure contains key information for healthcare professionals and contains the following:

- educational information
- therapy management advice to avoid foetal exposure to pomalidomide
- a distribution control system

- Safety advice of relevance to all patients.
- Process for follow-up of effectiveness of the measures described in this pack.
- Process for reporting adverse events and pregnancy in patients treated with pomalidomide.

Adverse Event Reporting Forms, an Algorithm and Risk Assessment Forms for obtaining consent are available through the Pathfinder PPP platform.

The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential are set out in the attached Algorithm.

1.3. Teratogenicity: Potential or Actual Foetal Exposure to pomalidomide

Pomalidomide must never be used by women who are able to become pregnant unless they follow the pomalidomide Pregnancy Prevention Programme described in this pack (Section 2.0).

Since pomalidomide may be present in the semen of male patients, all male and female patients must both follow effective contraceptive measures.

If a female patient or female partner of a male patient misses, or is suspected to have missed her period, or has any abnormality in menstrual bleeding, or suspects she is pregnant, then:

- Pomalidomide must be discontinued immediately, if a female patient.
- The woman must have a pregnancy test.
- If the pregnancy test is positive, the woman should be referred to a physician experienced in teratology for further evaluation and counselling.

Any positive pregnancy test or suspected foetal exposure to pomalidomide must be reported immediately to the Medicines and Healthcare products Regulatory Agency (MHRA) and to the relevant MAH . In this instance you must:

- Stop treatment immediately, if a female patient.
- Refer the patient/partner to a physician specialised or experienced in dealing with teratology for advice and evaluation.
    - Notify immediately:
        - PharmaCare Group Ltd. on 0330 043 0908; email Support@pharmacaregroup.co.uk, and

- the relevant MAH immediately, using:
  - the Pregnancy Reporting Form available within the Pathfinder PPP Platform, and
  - the contact details available within the Pathfinder PPP Platform or on the Great Britain (GB) and Northern Ireland (NI) electronic medicines compendium websites: www.medicines.org.uk/emc (for Great Britain) or www.emcmedicines.com/en-GB/northernireland (for Northern Ireland).

You can report the suspected pregnancy via:

- the Yellow Card website www.mhra.gov.uk/yellowcard,
- the MHRA Yellow Card app, available in the Google Play or Apple App Store, or
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

1.4. Safety Advice Relevant to all Patients

In addition to information about the Pregnancy Prevention Programme, this brochure contains important advice for healthcare professionals about how to minimise the risk of adverse events during treatment with pomalidomide.

For further information about the appropriate use and safety profile of pomalidomide please refer to the SmPC which can be found on the emc website: www.medicines.org.uk/emc (for Great Britain) or https://www.emcmedicines.com/en-GB/northernireland/ (for Northern Ireland).

You must complete every PAF via the online Pathfinder PPP platform and submit it immediately to PharmaCare Group Ltd., for ALL patients, regardless of indication or risk category. This is an absolute requirement so that the MAHs can fulfil their regulatory obligations to monitor PPP adherence and off-label usage.

Pomalidomide MAHs and PharmaCare Group Ltd are obliged to provide anonymised reports on this data to the MHRA, to assess the effectiveness of risk minimisation activities and will not be able to comply if pharmacies do not complete their PAFs or provide to PharmaCare Group Ltd., immediately.

An electronic copy of the Prescription Authorisation Form can also be found on the Pathfinder PPP platform.

2. Therapeutic Management Advice to Avoid Foetal Exposure

2.1. Women of Non-childbearing Potential (WNCBP)

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.
- Confirmed 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.

A female patient is considered to have childbearing potential unless she meets at least one of the above criteria. 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.

If a patient does not meet at least one of above criteria, but the prescriber considers the patient to be of nonchildbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from Pharmacare Group (Tel: 0330 043 0908, Email Support@pharmacaregroup.co.uk). The following information is required to assess whether a patient, who does not meet at least one of the above criteria, can be treated as a women of nonchildbearing potential:

- DOB and Initials of the Patient.
- Details of why the prescriber considers the patient to be of non-childbearing potential.
- Background to why a deviation has been requested.

2.2. Women of Childbearing Potential (WCBP)

Women of childbearing potential must never take pomalidomide if:

- Pregnant
- They are 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 teratogenic risk of pomalidomide, foetal exposure should be avoided.

Women of childbearing potential must understand the need to avoid pregnancy, and these patients must be adequately informed regarding the use of effective contraceptive measures every time a prescription is issued.

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. This must be followed unless the patient commits to absolute and continuous abstinence confirmed to her prescriber on a monthly basis.

If your patient is not established on effective contraception, she 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).

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 physician.

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

- The physician prescribing her method of contraception.
- The physician prescribing her pomalidomide.

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

Pregnancy Testing

For women of childbearing potential a pregnancy test must be performed prior to issuing a prescription. This may be embarrassing for some patients and may need to be handled sensitively. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

Women of childbearing potential (even if they have amenorrhoea) must 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 every 4 weeks 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 abstinence.

Patients who are being prescribed the appropriate contraceptive method by their physician, should inform their physician about pomalidomide treatment. Patients should be advised to inform you if a change or stop of method of contraception is needed.

A pregnancy test must be performed immediately if a patient misses her period, if there is any abnormality in menstrual bleeding, if she has heterosexual intercourse without using a contraceptive method, or if she suspects she is pregnant.

If a female patient has a positive pregnancy test, then:

- Stop treatment immediately.
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation.
- Notify immediately:

- PharmaCare Group Ltd. on 0330 043 0908; email Support@pharmacaregroup.co.uk, and
- the relevant MAH immediately, using:
  - the Pregnancy Reporting Form available within the Pathfinder PPP Platform, and
  - the contact details available within the Pathfinder PPP Platform or on the Great Britain (GB) and Northern Ireland (NI) electronic medicines compendium websites: www.medicines.org.uk/emc (for Great Britain) or www.emcmedicines.com/en-GB/northernireland (for Northern Ireland).

You can report the suspected pregnancy via:

- the Yellow Card website www.mhra.gov.uk/yellowcard,
- the MHRA Yellow Card app, available in the Google Play or Apple App Store, or
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

2.3. Men

In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided. Therefore, your male patients must be counselled at treatment initiation on the risks and benefits of pomalidomide therapy including the risk of birth defects, other side effects and important precautions associated with pomalidomide therapy. Inform your patient which are the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen. 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. Male patients should not donate semen or sperm during treatment, during dose interruptions and for at least 7 days following discontinuation of pomalidomide.

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 their 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.

You can report the suspected pregnancy via:

- the Yellow Card website www.mhra.gov.uk/yellowcard,
- the MHRA Yellow Card app, available in the Google Play or Apple App Store, or
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

2.4. Advice for all Patients

Your patient must be informed not to donate blood during or within 7 days after stopping treatment. If your patient discontinues therapy, they must return any unused pomalidomide to the pharmacy.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

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. Healthcare Professionals' Obligations

Healthcare Professionals have specific obligations that must be followed when prescribing or dispensing pomalidomide, which are:

Prescriber: You must ensure that

- Your patient is fully educated on the risks of pomalidomide.
- You complete the appropriate 'Risk Awareness Form' with your patient before the first prescription is issued.
- You provide the patient with a 'Patient Pocket Information Card', Patient Brochure and a copy of the 'Risk Awareness Form'.
- If relevant, your patient is using the appropriate method of contraception.
- Female patients of childbearing potential undergo a pregnancy test, which must be negative, before every prescription that you issue.
- You complete a PAF with every prescription:
  - this includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription.
- You prescribe pomalidomide in accordance with the measures described in this brochure and the SmPC which can be found on the emc website: www.medicines.org.uk/emc (for Great Britain) or https:// www.emcmedicines.com /en-GB/northernireland/ (for Northern Ireland).

Pharmacist: You must ensure that

- Your pharmacy is registered with the pomalidomide Pregnancy Prevention Programme. Registration will be valid for 2 years.
- Pomalidomide is only dispensed if the prescription is accompanied by a PAF. This includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription.
- You check and validate the PAF prior to dispensing pomalidomide.
- You dispense pomalidomide in accordance with the measures described in this brochure.
- You complete an on-line PAF via the Pathfinder PPP platform for every dispensing or in case of a temporary system unavailability, complete send immediately an off-line PAF to PharmaCare Group Ltd.
- You remind patients of key education messages each time pomalidomide is dispensed.

3.1. Information for Prescribers

3.1.1. Patient and Healthcare Professional Education

As the prescriber, you play a central role in ensuring that pomalidomide is used safely and correctly.

Most importantly, you will be helping to ensure that your patients understand the risks involved in taking pomalidomide and that they are aware of their responsibilities in preventing foetal exposure to the drug. In addition, you may need to help your patients understand the processes involved in the pomalidomide Pregnancy Prevention Programme. This will help to prevent any delays in your patients receiving their treatment.

If you refer your patient to a fertility expert (e.g. obstetrician or gynaecologist) for further contraceptive advice or pregnancy testing counselling, it is your responsibility to ensure that the fertility expert is aware of the pomalidomide Pregnancy Prevention Programme.

3.1.2. Patient Counselling and Education

Because of the different levels of risk, you will need to communicate different information to men, women and children. You must ensure that your patient understands the information before they complete their section of the Risk Awareness Form.

Please make use of the Patient Brochure and Patient Pocket Information Card to help explain the relevant information. Copies of the Brochure are available on the Pathfinder PPP platform, and your patient should take these materials home to read in their own time or with a relative. Further copies can be can be found in the Information for Patients page of the Pathfinder platform.

3.1.3. Prescribing Pomalidomide

3.1.3.1. 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 12 weeks. Do not dispense to a woman of childbearing potential unless the pregnancy test is negative and was performed within 3 days prior to the prescription.
- For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

3.1.3.2. 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 brochure and the SmPC, which can be found on the emc website: www.medicines.org.uk/emc (for Great Britain) or https://www.emcmedicines.com/en-GB/northernireland/ (for Northern Ireland).
- Obtain their written confirmation (using the correct Risk Awareness Form) that they have received and understood this information, and provide the patient with a copy.
- Provide the patient with a Patient Brochure and Patient Pocket Information Card.
- You must complete all necessary PAF fields in the Pathfinder PPP platform and provide the patient with only the prescription.

- In case of a temporary system unavailability, an off-line PAF must be completed with each pomalidomide prescription, and this will contain:
  - Patient initials, date of birth and diagnosis.
  - Prescriber name, signature and date.
  - Patient risk category (women of childbearing potential, women of non-childbearing potential, or male).
  - Confirmation that they have received counselling on the safe use of pomalidomide.
  - For women of childbearing potential, the pregnancy test date and result.

On completion of the PAF, the pharmacist will automatically receive it via the same system and will check this form prior to dispensing pomalidomide.

Once the PAF has been checked for completeness, a copy of the PAF must be sent to PharmaCare Group Ltd. (support@pharmacaregroup.co.uk), if a paper PAF is used.

3.1.3.3. Repeat of Subsequent Prescriptions

The patient must return to the prescriber for every repeat prescription of pomalidomide.

3.2. Information for Pharmacists

As a pharmacist you play an important role in ensuring that pomalidomide is used safely and correctly. Pomalidomide will only be supplied to pharmacies that have registered with the pomalidomide Pregnancy Prevention Programme. Pharmacies that only complete and approve PAFs and do not order or dispense pomalidomide will still need to register with the pomalidomide Pregnancy Prevention Programme.

3.2.1. Dispensing pomalidomide

It is a requirement of the pomalidomide Pregnancy Prevention Programme that pharmacies wishing to order and dispense pomalidomide are registered with the pomalidomide Pregnancy Prevention Programme platform. For pharmacies utilizing a third-party pharmacy to dispense the product to the patient, both the pharmacy completing and approving the PAF and the dispensing pharmacy are required to be registered with the pomalidomide Pregnancy Prevention Programme. Registration involves receiving access to the additional Risk Minimisation Materials via the Pathfinder PPP platform.

Dispensing of pomalidomide will only be allowed from pharmacies registered with the pomalidomide Pregnancy Prevention Programme. MAHs using this pomalidomide Pregnancy Prevention Programme will not authorise purchase and supply of pomalidomide to pharmacies not registered with the Pathfinder platform.

Pomalidomide is supplied to pharmacies registered with the Risk Minimisation Programme known as the pomalidomide Pregnancy Prevention Programme only for the purpose of dispensing the product by the PPP registered pharmacy to the patient.

In order to be registered, the Chief Pharmacist or appointed deputy of the institution wishing to dispense must agree to implement and audit the use of a PAF.

Along with each pomalidomide prescription, prescribers must complete a PAF and, for paper PAFs, instruct the patient to provide this to their pharmacy. You must only dispense pomalidomide if the prescriber has annotated this form correctly.

When completing the PAF, it asks the prescriber to confirm:

- The patient's diagnosis.
- The patient's risk category.
- 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 prescription.
- If the patient's risk category is male, counselling regarding the use of condoms has taken place.
- That a Risk Awareness Form has been completed by the patient.
- That the prescriber has read and understood the contents of all pomalidomide Pregnancy Prevention Programme materials.

When completing the PAF, it asks the pharmacist to confirm:

- That the PAF has been completed in full by the prescriber.
- That the supply dispensed is no more than a 4-week supply for a WCBP and no more than a 12-week supply for male and WNCBP patients.
- The dispensing for women of childbearing potential is taking place within 7 days of the prescription date.
- That the pharmacist has read and understood the contents of all pomalidomide Pregnancy Prevention Programme materials.

For women of childbearing potential, prescriptions for pomalidomide should be limited to a maximum duration of 4 weeks and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

Pharmacies are required to complete a PAF via the Pathfinder PPP platform for every dispensing or in case of a temporary system unavailability, send an off-line PAF immediately after dispensing to PharmaCare Group Ltd. immediately after dispensing (support@pharmacaregroup.co.uk) .

Pharmacies should retain the original off-line paper PAF, if used in case of system unavailability, at the pharmacy premises for a minimum of 2-years.

3.2.2. Dispensing Advice

- Please ensure that you dispense pomalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles.
- For each prescription, dispense a maximum of a 4week supply for women of childbearing potential or a 12 week supply for all other patients.
- Please educate all pharmacists within your pharmacy about the dispensing procedures for pomalidomide.
- 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.

4. Follow-up Assessment of the Effectiveness of the Programme

The terms of the pomalidomide Marketing Authorisation require every MAH 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 pregnancy exposure in patients treated with pomalidomide.

PharmacareGroup Inc. as an administrator of the system is therefore monitoring the effectiveness of the programme at regular intervals and reports the results appropriately (anonymously and aggregated) to the MAHs and MHRA. Pharmacare Group conducts the audit from all of the completed PAFs received.

Pharmacies must complete via the pomalidomide PAF immediately after dispensing the product via the Pathfinder PPP platform. Pharmacare Group Ltd. will be able to review all PAFs. It is critical, therefore, that PAFs are completed accurately and that physicians and pharmacies thereby assist Pharmacare Group Ltd. to audit the effectiveness of the Prevention Programme as implemented in the UK.

Pomalidomide MAHs and PharmaCare Group Ltd are obliged to provide the anonymised reports on the data received from the PAFs to the regulatory agencies. The reports are used to assess the effectiveness of risk minimisation activities and they will not be able to comply if pharmacies do not complete their PAFs or provide ALL their PAFs to PharmaCare Group Ltd. immediately.

An electronic copy of the PAF can also be found on the the Pathfinder PPP platform.

5. Safety Advice Relevant to all Parties

The following section contains advice to Healthcare Professionals about how to minimize the risk of thrombocytopenia and cardiac failure associated with the use of pomalidomide. Please refer also to SmPC (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 neutropenia and thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

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

5.1. Risk of Thrombocytopenia and Cardiac Failure with pomalidomide

5.1.1. Thrombocytopenia

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide.

It is therefore encouraged to monitor complete blood counts - 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
<u>Thrombocytopenia</u> • 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.

5.1.2. 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).

5.2. Safety and Off-Label Use

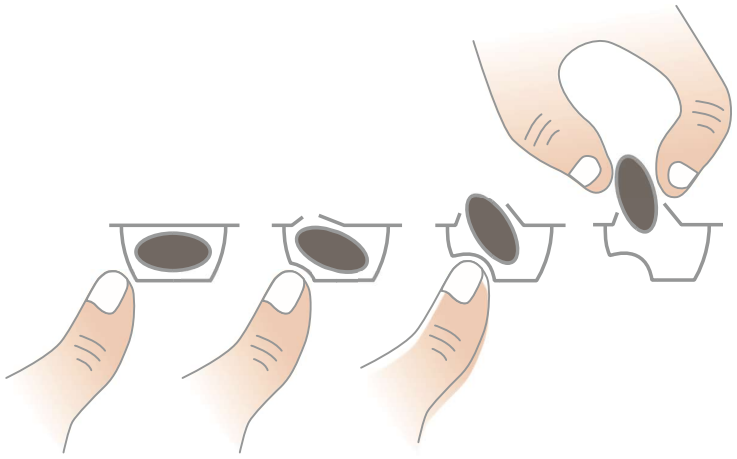
Please note that the posology, adverse event profile and recommendations outlined above, relate to the use of pomalidomide within its licensed indication. Pomalidomide must always be used according to the Pregnancy Prevention Programme described in this pack – these precautions must be followed, irrespective of the treatment setting, including the indication for treatment. It is essential that the patient's diagnosis is entered on the PAF - this will allow an assessment of the clinical usage of pomalidomide, which is important for ongoing monitoring of safety.

5.3. 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 capsules 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 requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a healthcare professional or caregiver.

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule).

- Use proper technique when removing gloves to prevent potential skin exposure (see overleaf).
- Place gloves in a sealable plastic polyethylene bag and dispose them according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Patients should be advised never to give the medicinal product to another person.

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

- If outer carton is visibly damaged – Do Not Open
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking – Close Outer Carton Immediately
- Place the product inside a sealable plastic polyethylene bag.
- Return unused pack to the pharmacist for safe disposal as soon as possible.

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

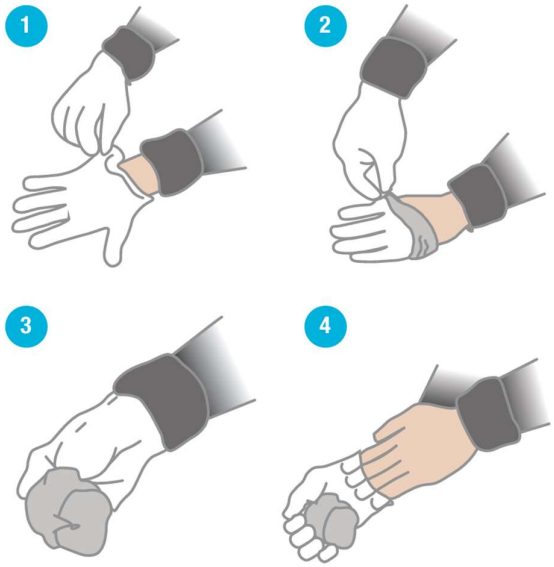
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the relevant MAH immediately using the contact details available in the Pathfinder Pregnancy Prevention Programme (PPP) platform or on the Great Britain (GB) and Northern Ireland (NI) electronic medicines compendium websites: www.medicines.org.uk/emc (for Great Britain) or www.emcmedicines.com/en-GB/northernireland (for Northern Ireland).

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, be 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.



5.4. 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.

6. Reporting Adverse Events, Suspected and Confirmed Pregnancies, and Foetal Exposures

The safe use of pomalidomide is of paramount importance.

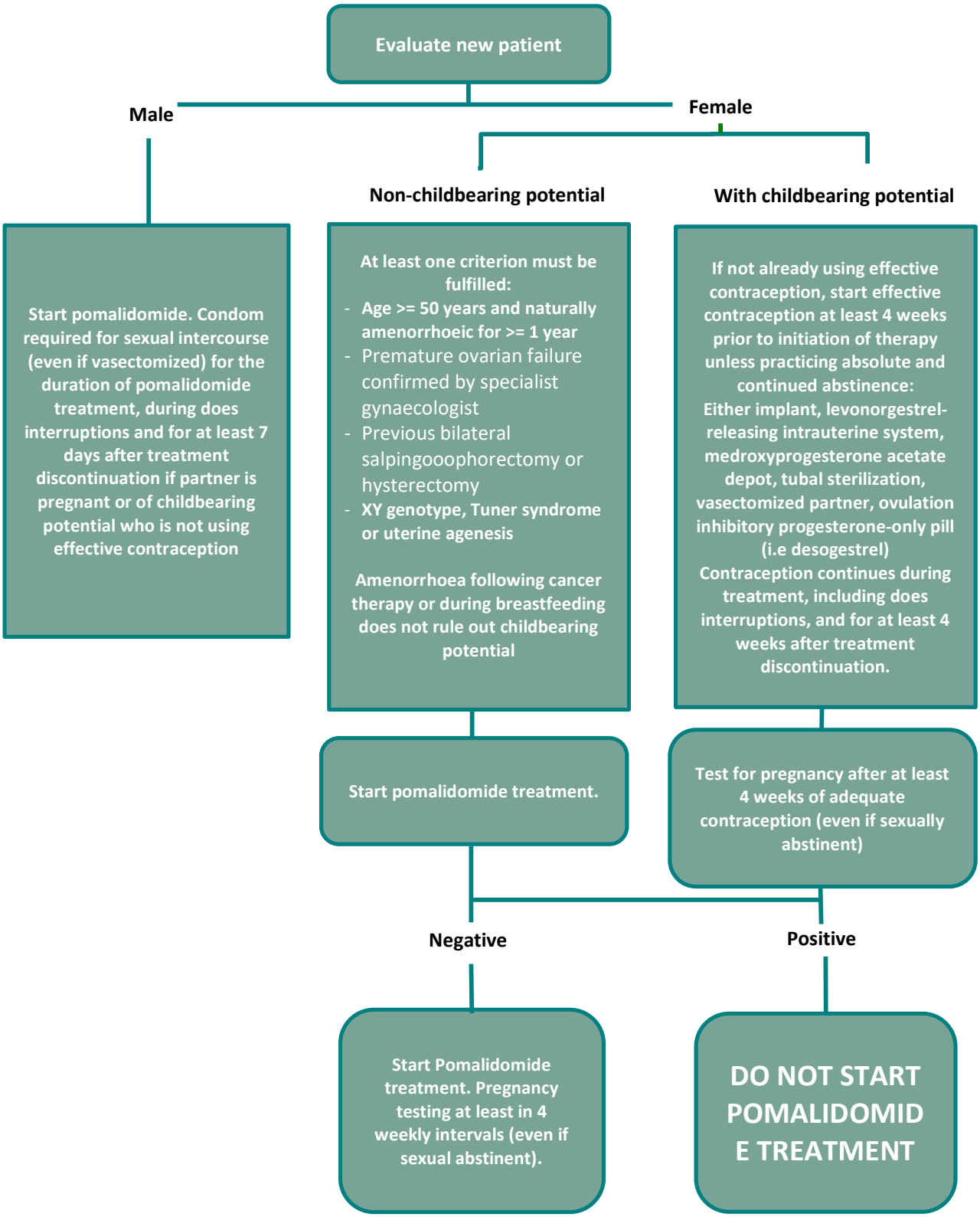
Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Adverse Event Report forms and Pregnancy Reporting forms are available in available in the Pathfinder Pregnancy Prevention Programme (PPP) platform and should be forwarded to the Pathfinder Pregnancy Prevention Programme (PPP) platform and should be forwarded to the relevant MAH immediately using the contact details also available in the Pathfinder Pregnancy Prevention Programme (PPP) platform or on the Great Britain (GB) and Northern Ireland (NI) electronic medicines compendium websites: www.medicines.org.uk/emc (for Great Britain) or www.emcmedicines.com/en-GB/northernireland (for Northern Ireland).

You can report the adverse event or suspected pregnancy via:

- **the Yellow Card website www.mhra.gov.uk/yellowcard,**
- **the MHRA Yellow Card app, available in the Google Play or Apple App Store, or**
- **some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.**

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

7. Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



8. Contact Details

Pathfinder PPP Platform technical Queries:

For technical information and questions on the Pathfinder, please contact:

HealthBeacon

Email: clientsupport@healthbeacon.com

Tel: +44 203 936 8807

Mon - Fri 9am - 5pm GMT

Pathfinder PPP Platform Administrative Queries:

For information and questions on the Risk Management of Pomalidomide, the Pregnancy Prevention Programme, please contact:

Pharmacare Group

Email: support@pharmacaregroup.co.uk

Tel: 0330 043 0908

Mon - Fri 9am - 5pm GMT

Medical Information and Adverse Event

To report any Adverse Events or suspected pregnancies, or to obtain Medical Information on the respective medicinal product from the relevant Marketing Authorisation Holder, please find the contact details of each participating MAH in the Pathfinder PPP platform

Data Protection Contact Details

Personal data is used solely for the purpose of entering you into the Pregnancy Prevention Programme and is processed by the relevant marketing authorisation holder, as marketing authorisation holder of pharmaceutical products and by the third-party service provider HealthBeacon and Pharmacare Group, to the extent and 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 support@pathfinderrmp.co.uk