Pomalidomide Krka (Pomalidomide)

Healthcare Professionals Information Guide

IRELAND

Version 01

Important Safety Information:

Healthcare Professionals involved in the prescribing or dispensing of pomalidomide must read and understand the information contained within this Guide

For complete safety information, please refer to the Summary of Product Characteristics (SmPC) for Pomalidomide Krka available via the HPRA website: www.hpra.ie or on the EMA Website: www.ema.europa.eu

Risk Management contact details:
Telephone: +353 1 413 3710
Email: Info.IE@krka.biz *or* pharmacovigilance.IE@krka.biz

Medical Information Queries:
Telephone: +353 1 413 3710
Email: pharmacovigilance.IE@krka.biz

Data Protection Queries:
Telephone: +353 1 413 3710
Email: Info.IE@krka.biz

IE/ver1.0; Date of texts preparation: June 2024; HPRA Approved: September 2024

Contents

Introduction

Pomalidomide Krka (Pomalidomide)

Pregnancy Prevention Programme
and
Information for Healthcare Professionals
Prescribing or Dispensing Pomalidomide

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.

For full information regarding the requirements of the PPP, as well as safety information, side effects and recommended precautions please refer to the Pomalidomide Krka Summary of Product Characteristics (SmPC). This can be found on the HPRA website: www.hpra.ie and EMA website: www.ema.europa.eu

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 HPRA website: www.hpra.ie and EMA website: www.ema.europa.eu

Pomalidomide – Risk of Teratogenicity

Pomalidomide is an immunomodulating medicinal product. 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 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.

The Pomalidomide Pregnancy Prevention Programme

Pregnancy Prevention 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 Pomalidomide Krka 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 'Pomalidomide Krka' under 'Find a medicine' and click 'EdM' under the 'documents' column) and EMA website: www.ema.europa.eu.

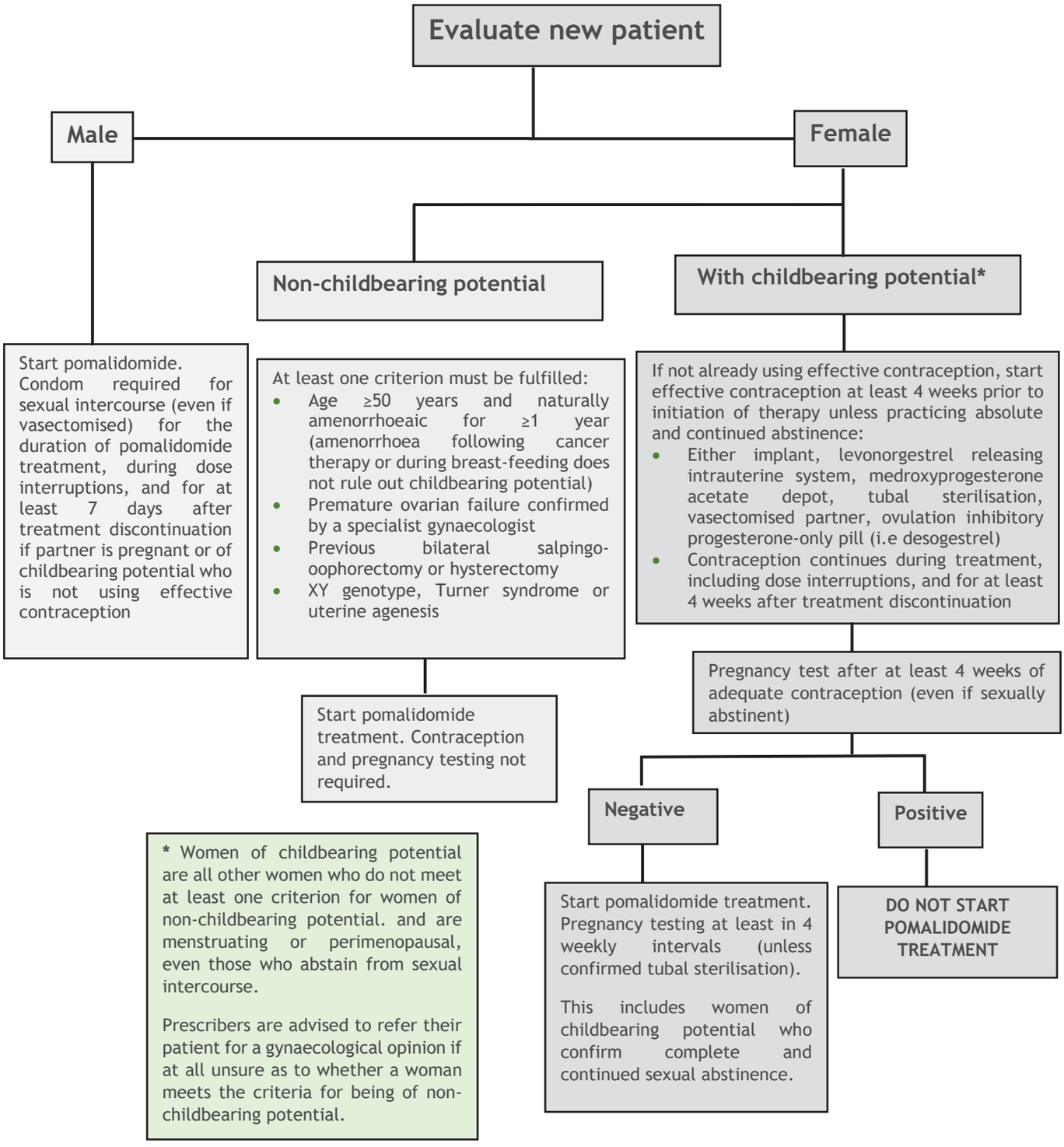
In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of Pomalidomide Krka will only be allowed from pharmacies registered with KRKA. KRKA will not authorise supply of Pomalidomide Krka to pharmacies that are not registered with KRKA.

The following are core requirements of the Pregnancy Prevention Programme:

- A controlled access programme.
- All healthcare professionals prescribing or dispensing pomalidomide must read and understand the Healthcare Professional’s Information Guide.
- Every prescription for pomalidomide must be accompanied by a Prescription Authorisation Form, which must be completed and signed by the prescriber and checked and counter-signed by the pharmacist.
- All pharmacies who intend to dispense Pomalidomide Krka must agree to implementing risk minimisation by registering with the KRKA Pregnancy Prevention Programme.

The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out below

Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



Safety Advice to Avoid Foetal Exposure

PPP Advice for Women of Non-Childbearing Potential

Determine if a woman is of 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 (amenorrhoea following cancer therapy or during breast-feeding does not rule out childbearing potential)
- Confirmed premature ovarian failure if confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis

Women of childbearing potential are all other women who are menstruating or perimenopausal, even those who abstain from sexual intercourse.

Prescribers are advised to refer their patient for a gynaecological opinion if unsure whether or not she meets the criteria for being of non-childbearing potential.

PPP Advice for Women of Childbearing Potential

Women of childbearing potential must never take pomalidomide if:

- 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, and even in case of dose interruption **or**
  - commit to absolute and continuous sexual abstinence, confirmed on monthly basis
    AND
  - have a medically supervised negative pregnancy test (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 continuous sexual abstinence.

There must be **no more than 3 days** between the dates of the last negative pregnancy test and the prescription. Best practice is for the pregnancy test, prescribing and dispensing to take place on the same day.

If not established on effective contraception, the patient must be referred to an appropriately trained healthcare professional for contraceptive advice in order that contraception can be initiated.

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 prescriber 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 PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE

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

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

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

Your patient should be advised that if a pregnancy does occur whilst she is receiving pomalidomide, she must stop treatment immediately and 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 Krka:

- **Stop treatment immediately**
- **Refer the patient to a physician specialised or experienced in teratology for evaluation and advice**
- **Notify KRKA immediately of all such occurrences by contacting KRKA (Telephone: +353 1 413 3710; Email: pharmacovigilance.IE@krka.biz). Please also complete the Pregnancy Reporting Form. KRKA will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases**
- **Suspected pregnancies can also be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance website: www.hpra.ie**

PPP Advice for Men

- In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided.
- Inform your patient about the effective contraceptive methods that his female partner can use.
- Pomalidomide is present in semen. Therefore all male patients 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 who is not using effective contraception and even if the male patient has undergone vasectomy.
- Patients should be instructed that if their partner becomes 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 docter 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 7 days following discontinuation of pomalidomide.

If the partner of a male taking Pomalidomide Krka becomes pregnant, 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 KRKA immediately of all such occurrences by contacting KRKA (Telephone: +353 1 413 3710; Email: pharmacovigilance.IE@krka.biz). Please also complete the Pregnancy Reporting Form. KRKA will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.**
- **Suspected pregnancies can also be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance website: www.hpra.ie.**

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.

Points to consider for handling the medicinal product: for patients, healthcare professionals and caregivers

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

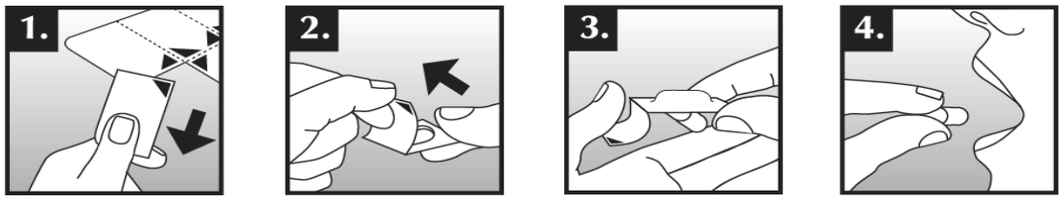
Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule.

Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

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

To remove the Pomalidomide Krka capsule from the blister:

1. Hold the blister at the edges and separate one blister cell from the rest of the blister by gently tearing along the perforations around it.
2. Pull up the edge of the foil and peel the foil off completely.
3. Tip the capsule out onto your hand.
4. Swallow the capsule whole, preferably with water.



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

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

If a drug product 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 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 tell your doctor and / or pharmacist immediately or please report to KRKA (Phone number: +353 1 413 3710; Email: pharmacovigilance.IE@krka.biz).

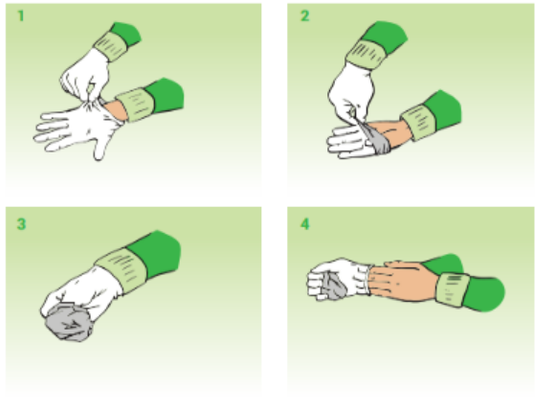
If the contents of the capsule are attached to the skin or mucous membranes

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

Proper Technique for Removing Gloves

Gloves should be removed carefully to prevent skin exposure and disposed of in accordance with local requirements.

- 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



Prescribing and Dispensing Pomalidomide

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

Maximum Prescription Lengths

- **Prescriptions for women of childbearing potential** can be for a maximum duration of 4 weeks according to the approved indications dosing regimens (posology).
- **For all other patients (women of non-childbearing potential or male)**, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

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 HPRA website: www.hpra.ie and EMA website: www.ema.europa.eu
- Obtain written confirmation (using the Risk Awareness Form for the appropriate patient category) that they have received and understood this information, and provide the patient with a copy
- Ensure that your patient is using an effective method of contraception, if appropriate
- 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 patient's nominated pharmacy on the first occasion that the patient is being prescribed pomalidomide.

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 or submit electronically to the pharmacy with each pomalidomide prescription.

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

Prescription Authorisation Form

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

The prescriber must confirm the following on the Prescription Authorisation Form:

- Patient initials, date of birth and the indication for which pomalidomide is being prescribed
- Name of treating hospital, prescriber name, supervising physician name, signature and date
- Confirmation that they have provided counselling on the teratogenic risk of pomalidomide and the required contraceptive measures for women of childbearing potential and male patients
- Whether the patient is male, a woman of childbearing potential or a 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 Professional's Information Guide
- That the information provided on this 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.

The pharmacist must confirm the following on the Prescription Authorisation Form:
- That the Prescription Authorisation Form has been completed in full by the prescriber
- That dispensing for a woman of childbearing potential is taking place **7 days or less** from the date of prescribing
- That the pharmacist is dispensing the appropriate supply for the patient category
- That the pharmacist has read and understood the contents of the Healthcare Professional's Information Guide

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.

Dispensing Pomalidomide Krka

Registration

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense Pomalidomide Krka are registered with KRKA. Registration involves reading and understanding the Healthcare Professional's Information Guide, completing and signing the Pharmacy Registration Form, and emailing the completed form to indicate agreement and compliance with the content.

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

Dispensing of Pomalidomide Krka will only be allowed from pharmacies registered with KRKA. KRKA will not authorise purchase and supply of pomalidomide to pharmacies not registered with KRKA.

Pomalidomide Krka is supplied to pharmacies registered with KRKA's Pregnancy Prevention Programme (PPP) only for the purpose of dispensing the product by the PPP registered pharmacy to the patient.

Community Pharmacy Dispensing

A pomalidomide 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 community pharmacy will need to register with the Pomalidomide Pregnancy Prevention Programme for the manufacturer of any products it will be dispensing prior to being able to order those pomalidomide product for your patient and dispense them. If the nominated pharmacy is not already authorised to supply Pomalidomide Krka, it must first contact KRKA to register with them using the **Pomalidomide Krka (pomalidomide) Pharmacy Registration Form**. KRKA 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.

Ordering of pomalidomide

The pharmacy must be registered with KRKA to order Pomalidomide Krka. To order Pomalidomide Krka the pharmacy must use a specific Pomalidomide Krka (pomalidomide) Order Form (available on request from KRKA and electronically for download on the HPRA website: www.hpra.ie). The pharmacy must write the name of the prescriber on their Order Form when placing an order for pomalidomide.

Dispensing Advice

For women of childbearing potential

- the date of the last negative pregnancy test, must be within the 3 days prior to the date of the prescription.
- dispensing of 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 should be limited to 4 weeks of treatment and continuation of treatment requires a new prescription.

For males and women of non-childbearing potential

- prescriptions of pomalidomide should be limited to 12 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 capsules to the pharmacy. Pharmacies must accept any unused pomalidomide capsules 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 for the PPP and the dispensing procedures for pomalidomide.

Monitoring the Effectiveness of the Programme and Monitoring of Off-Label Use

The terms of the Pomalidomide Krka Marketing Authorisation require KRKA to assess the effectiveness of the Pregnancy Prevention Programme (PPP) in order to ensure that all reasonable steps are being taken to reduce the risk of foetal exposure to pomalidomide as well as to monitor off-label use.

KRKA have agreed with the HPRA that pharmacies can fulfil their obligations in this respect, by conducting a manual self-audit of the Prescription Authorisation Forms, against which the pharmacy has dispensed Pomalidomide Krka and reporting the results to KRKA. This information will be provided in an anonymous and aggregated format to the HPRA.

KRKA will supply pharmacies who are registered with KRKA with an Audit Form, such that annual self-auditing of the pharmacies and feedback of the audit results to KRKA can occur.

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

Other Selected Risks of Pomalidomide Krka

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.

Risk of thrombocytopenia and cardiac failure with pomalidomide

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
<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.

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).

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.

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

The safe use of pomalidomide is of paramount importance.

As part of KRKA's ongoing safety monitoring, the company wishes to learn of Adverse Events that have occurred during the use of Pomalidomide Krka. 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 KRKA Medical Information. For any pregnancy reports, the Pregnancy Reporting Forms for Pomalidomide Krka available as part of the Healthcare Professionals' Information Pack should be completed and forwarded to KRKA Medical Information (Telephone: +353 1 413 3710; Email: pharmacovigilance.IE@krka.biz)

Prescribers Guide to Prescribing Pomalidomide Schematic

In order to initiate therapy with pomalidomide:

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

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

For the FIRST prescription of pomalidomide Follow steps 1 to 4

1. Prescribers wishing to prescribe pomalidomide must read the Healthcare Professional's Information Guide

2. Please complete **a Pomalidomide Community Pharmacy Dispensing Notification Form** to notify the nominated community pharmacy that their patient will be presenting with a prescription for pomalidomide. Fax/E-mail this form to the Nominated Community Pharmacy.

For SUBSEQUENT prescriptions of pomalidomide Follow steps 3 to 4

3. Prescribe pomalidomide using 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 pomalidomide must be accompanied by a **Pomalidomide Prescription Authorisation Form.**

Pharmacists Guide to Dispensing Pomalidomide Schematic

In order to dispense Pomalidomide Krka:

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 Community Pharmacy that has NOT previously registered with KRKA

1. Contact KRKA on Info.IE@krka.biz/ pharmacovigilance.IE@krka.biz to obtain a Healthcare Professional's Information Guide which includes all relevant information, Pharmacy Registration Form and Order Form (if you have not already received these materials).
2. Read the Guide.
3. Complete **Pharmacy Registration Form** and Email to KRKA on Info.IE@krka.biz/ pharmacovigilance.IE@krka.biz. You will be notified when you have been registered.
4. Once you are informed that you are registered with KRKA, complete a **'Pomalidomide Krka (pomalidomide) Order Form'.**
5. Fax/Email **'Pomalidomide Krka (Pomalidomide) Order Form'** to UDD on 01 463 2404/ SpecialOrders@united-drug.com. UDD aim to deliver complete orders placed before 13:30 Monday - Friday on the customers' next available route as per customers' current delivery arrangements with United Drug Wholesale.

   And

6. For orders through Uniphar, email 'Pomalidomide Krka (pomalidomide) Order Form' to KRKA on Info.IE@krka.biz

You are a Community Pharmacy that has previously registered with KRKA

1. Complete a '**Pomalidomide Krka (pomalidomide) Order Form'.**
2. Fax/Email **'Pomalidomide Krka (pomalidomide) Order Form'** to UDD on 01 463 2404/SpecialOrders@united-drug.com. UDD aim to deliver complete orders placed before 13:30 Monday - Friday on the customers' next available route as per customers' current delivery arrangements with United Drug Wholesale.

Or

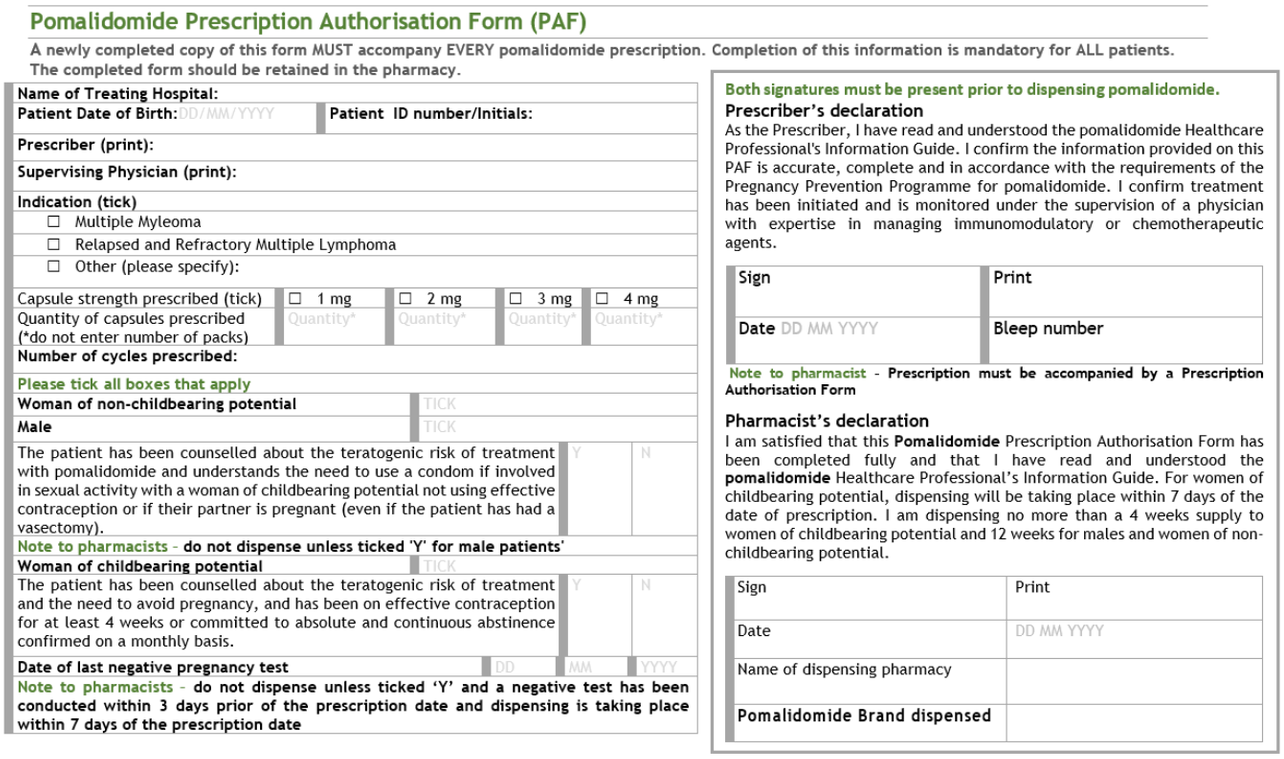
3. For orders through Uniphar, email 'Pomalidomide Krka (pomalidomide) Order Form' to KRKA on Info.IE@krka.biz

Note. 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 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

A Guide to Completing the Prescription Authorisation Form (PAF)

This Guide will help you complete the pomalidomide Prescription Authorisation Form. The form is used within the Pregnancy Prevention Programme (PPP) and must be completed each time you prescribe or dispense pomalidomide.



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 the pharmacy.

Name of Treating Hospital:

Patient Date of Birth: DD/MM/YYYY | **Patient ID number/Initials:**

Prescriber (print):

Supervising Physician (print):

Indication (tick)

☐ Multiple Myeloma

☐ Relapsed and Refractory Multiple Lymphoma

☐ Other (please specify):

Capsule strength prescribed (tick)	☐ 1 mg	☐ 2 mg	☐ 3 mg	☐ 4 mg
Quantity of capsules prescribed (*do not enter number of packs)	Quantity*	Quantity*	Quantity*	Quantity*

Number of cycles prescribed:

Please tick all boxes that apply

Woman of non-childbearing potential	TICK		
Male	TICK		
The patient has been counselled about the teratogenic risk of treatment with 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 pharmacists – do not dispense unless ticked 'Y' for male patients'

Woman of childbearing potential	TICK		
The patient has been counselled about the teratogenic risk of treatment and the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.		Y	N
Date of last negative pregnancy test	DD	MM	YYYY

Note to pharmacists – do not dispense unless ticked 'Y' 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 pomalidomide Healthcare Professional's Information Guide. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme for pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician with expertise in managing immunomodulatory or chemotherapeutic agents.

Sign	Print
Date DD MM YYYY	Bleep number

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

Pharmacist's declaration

I am satisfied that this **Pomalidomide** Prescription Authorisation Form has been completed fully and that I have read and understood the **pomalidomide** Healthcare Professional's Information Guide. 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 weeks supply to women of childbearing potential and 12 weeks for males and women of non-childbearing potential.

Sign	Print
Date	DD MM YYYY
Name of dispensing pharmacy	
Pomalidomide Brand dispensed	

IE/ver1.0; Date of texts preparation: June 2024; HPRA Approved: August 2024 1/1

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).

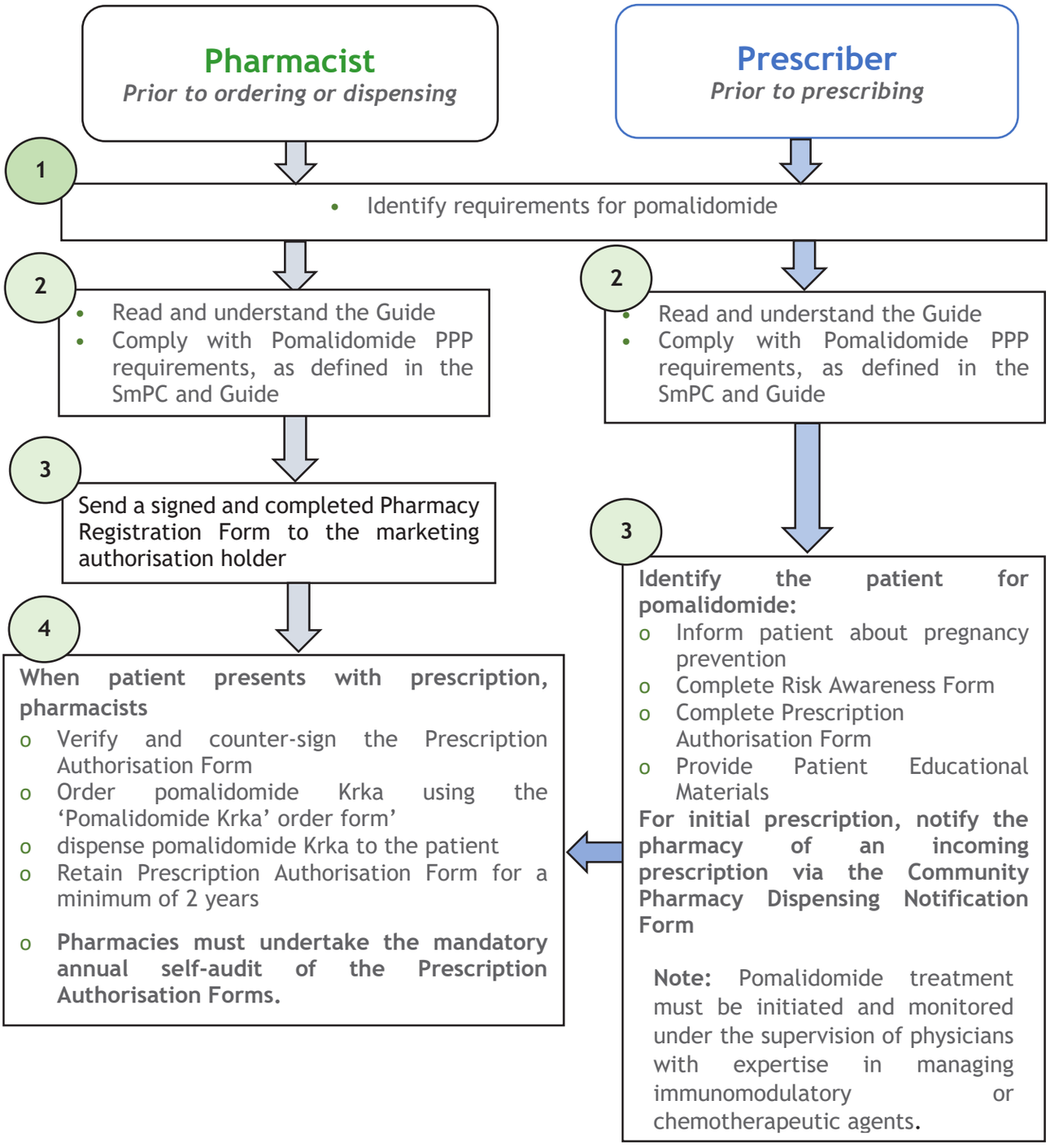
C. Check the form is complete and legible.

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.
   a. Dispense only a maximum of 4 weeks supply for women of childbearing potential at any one time.
   b. Dispense only a maximum of 12 weeks supply for Males and Women of Non-childbearing Potential.

E. Ensure you record the brand of Pomalidomide dispensed for each dispensing cycle the PAF was used for. You will need this for completion of the pharmacy self-audit for the particular Pomalidomide brand.

Further information and materials are available from KRKA
Telephone: +353 1 413 3710
Email:Info.IE@krka.biz or pharmacovigilance.IE@krka.biz

Prescribing and Dispensing of Pomalidomide Schematic



Frequently Asked Questions (FAQs)

What must I do prior to prescribing pomalidomide?
Prescribers wishing to prescribe pomalidomide must read the pomalidomide Healthcare Professional's Information Guide. Hardcopies are available directly from KRKA and the Guide is also available electronically on the HPRA website www.hpra.ie.
A Prescription Authoristion Form must be completed and accompany each prescription for pomalidomide.

What are the maximum prescription lengths for treatment with pomalidomide?
The maximum prescription lengths for treatment with pomalidomide is 4 weeks for Women of Childbearing Potential patients and 12 weeks for Males and Women of Non-Childbearing Potential patients.

What must I do prior to ordering or dispensing pomalidomide?
Pharmacies choosing to purchase or dispense Pomalidomide Krka must register with KRKA using the Pomalidomide Krka (pomalidomide) Pharmacy Registration Form. Signed Completed Pharmacy Registration Forms should be sent via email (Info.IE@krka.biz **or** pharmacovigilance.IE@krka.biz) to indicate agreement and compliance with the content. Once you have returned a completed Pharmacy Registration Form, KRKA will inform the distributors who will place you on the registered list.
If you have not already received these materials and are not already registered with KRKA, obtain the Guide, Pharmacy Registration Form, Order Form and other needed materials by contacting KRKA. We will send the pharmacy the relevant documentation.
A Prescription Authoristion Form must be completed and accompany each prescription for pomalidomide.

Do I need a registration number to order pomalidomide?
No, you just need to register with KRKA by returning the Pharmacy Registration Form. We will register you and inform the distributor that you are registered, and can receive Pomalidomide Krka.

Where do I order Pomalidomide Krka?
Once registered with KRKA, to order Pomalidomide Krka please contact our distributors. You must have returned the Pharmacy Registration Form to KRKA before you can place an order. You will need to complete the Pomalidomide Krka (pomalidomide) Order Form and fax or email your order to the distributors.

Distributors:

United Drug Distribution (UDD)
United Drug House
Magna Business Park
Citywest Road, Dublin 24

Telephone: 01 463 2478
Fax: 01 463 2404
Email: SpecialOrders@united-drug.com

Or

Uniphar Group
4045 Kingswood Road
Citywest Business Park
Co. Dublin, D24 VO6K

Reception Telephone: 01 428 7777
Customer Service: 01 468 7501
Email: RepsOrders@uniphar.ie
Orders Email: Info.IE@krka.biz

Where can I get further copies of the Pomalidomide Krka Healthcare Professional's Information Guide or the patient materials?
If you would like further copies of the Pomalidomide Krka Healthcare Professional's Information Guide or any other materials for healthcare professionals or patients, please telephone or email KRKA using the contact details below, or by speaking to any KRKA representative. Electronic copies of the materials are also available on the HPRA website: www.hpra.ie.
Telephone: +353 1 413 3710
Email: Info.IE@krka.biz ***or*** pharmacovigilance.IE@krka.biz

How should I report an Adverse Event or a Suspected Pregnancy?
Adverse Events and Suspected Pregnancies (using the Krka pregnancy reporting form available in the Healthcare Professionals Information Pack or electronically at www.hpra.ie) should be reported to KRKA Pharmacovigilance using the contact details below:
Telephone: +353 1 413 3710
Email: pharmacovigilance.IE@krka.biz

Suspected adverse reactions can also be reported via the Health Products Regulatory Authority (HPRA) Pharmacovigilance Website: www.hpra.ie.

How will KRKA audit pharmacies register for the KRKA Pregnancy Prevention Programme?
The terms of the KRKA 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 KRKA approving the registration of pharmacies and thereby granting authorisation to procure pomalidomide.

KRKA have agreed with the HPRA that pharmacies can fulfill their obligations in this respect, by conducting a manual self- audit of the Prescription Authorisation Forms, against which the pharmacy has dispensed Pomalidomide Krka and reporting the results to KRKA. This information will be provided, in an anonymised and aggregated format, to the HPRA. KRKA will supply pharmacies with an Audit Form, such that annual self-auditing of pharmacies and feedback of the audit results to KRKA can occur. KRKA will contact the pharmacy in cases where there are irregularities or queries on Audit Form so that any potential problems or errors can be dealt with as they arise.

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 KRKA Order Forms that registered pharmacies must complete to place an order will be forwarded to KRKA Risk Management by UDD. As agreed with the HPRA, KRKA Risk Management will compile anonymised and aggregated data reports using the information recorded on each Order Form to provide to the HPRA on annual basis.
KRKA will keep the Order Forms for orders through Uniphar and will provide Uniphar with a copy.

It is therefore critical for pharmacies to ensure that KRKA Order Forms are completed accurately and fully.

Where and how do I submit a Self-Audit Form?
Please send a completed Audit Form to KRKA annually via email: pharmacovigilance.IE@krka.biz (scanned completed form as an attachment or complete the modifiable PDF file that will be sent by KRKA annually).

What are the contact details for KRKA?
To contact KRKA, please telephone or email the KRKA using the contact details below:
Telephone: +353 1 413 3710
Email: pharmacovigilance.IE@krka.biz

For information and questions on the Risk Management of KRKA products, the Pregnancy Prevention Programme, Pharmacy Registrations, the use of the Prescription Authorisation Form and to order hard copies of any of the Pomalidomide Krka Pregnancy Prevention Plan materials
Telephone: +353 1 413 3710
Email: Info.IE@krka.biz ***or*** pharmacovigilance.IE@krka.biz

For Data Protection Queries
Telephone: +353 1 413 3710
Email: Info.IE@krka.biz

Contact Details

Risk Management:
For information and questions on the Risk Management of KRKA products, Pomalidomide Krka Pregnancy Prevention Programme, Pharmacy Registrations, and the use of the Prescription Authorisation Form and to order hard copies of any of the Pomalidomide Krka Pregnancy Prevention Plan materials:

Telephone: +353 1 413 3710
Email: Info.IE@krka.biz *or* pharmacovigilance.IE@krka.biz

Medical Information:
To report any Adverse Events or Suspected Pregnancies, or to obtain Medical Information on Pomalidomide KRKA products.

Telephone: +353 1 413 3710
Email: pharmacovigilance.IE@krka.biz

Suspected adverse reactions can also be reported via the HPRA Pharmacovigilance website: www.hpra.ie.

Data Protection:
Telephone: +353 1 413 3710
Email: Info.IE@krka.biz

Distributors:
For product delivery enquiries.

United Drug Distribution (UDD)
United Drug House
Magna Business Park
Citywest Road, Dublin 24

Telephone: 01 463 2478
Fax: 01 463 2404
Email: SpecialOrders@united-drug.com

Or

Uniphar Group
4045 Kingswood Road
Citywest Business Park
Co. Dublin, D24 VO6K

Reception Telephone: 01 428 7777
Customer Service: 01 468 7501
Email: RepsOrders@uniphar.ie
Orders Email: Info.IE@krka.biz

IE/ver1.0; Date of texts preparation: June 2024; HPRA Approved: September 2024