Pomalidomide Krka (Pomalidomide)

Healthcare Professionals Information Pack

IRELAND

Version 01

Important Safety Information:

Healthcare Professionals involved in the prescribing or dispensing of pomalidomide must read and understand the information contained within the Healthcare Professionals' Information Pack.

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

The Healthcare Professionals' Information Pack contains the information and materials needed for the prescribing and dispensing of pomalidomide, including information about the Pregnancy Prevention Programme.

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

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance at www.hpra.ie. Adverse reactions should also be reported to KRKA on +353 1 413 3710 or Info.IE@krka.biz or pharmacovigilance.IE@krka.biz

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

Pomalidomide Krka (pomalidomide)

Healthcare Professional's Information Pack

IRELAND

This pack contains the following contents:

Healthcare Professional Information Guide

This Guide contains safety information for the Healthcare professional and guidance on how to prescribe and dispense Pomalidomide Krka according to the Pomalidomide Krka Pregnancy Prevention Programme

Patient Guide

This section contains information about pomalidomide that you should give to your patients

Patient Pocket Information Card

Risk Awareness Form

Complete the relevant section in the form before prescribing pomalidomide to your patients, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male

Prescription Authorisation Form

Complete a Prescription Authorisation Form with every prescription for pomalidomide

Community Pharmacy Dispensing Notification Form

Use this form to advise the patient's nominated community pharmacy that will shortly be receiving an initial prescription for pomalidomide

Pharmacy Registration Form

Dispensing Pharmacy needs to complete the registration form in order to obtain or dispense Pomalidomide Krka

Pharmacy Order Form

Use this Order Form to order Pomalidomide Krka

Pregnancy Reporting and Pregnancy Outcome Forms

Please report Suspected and Confirmed Pregnancies, and Foetal Exposure. This section contains forms you can use

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

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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.

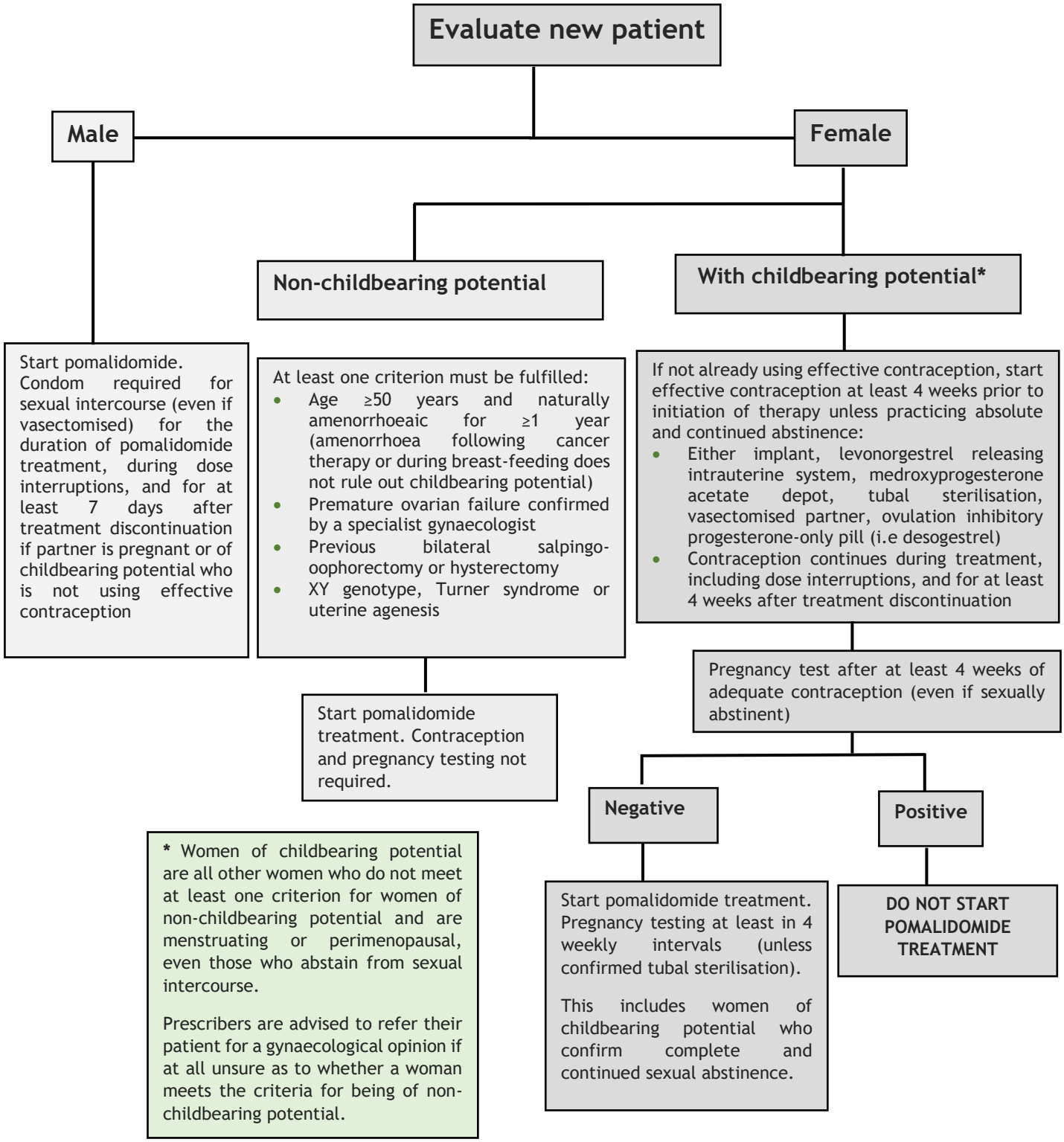
In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of Pomalidomide Krka will only be allowed from pharmacies registered with KRKA. KRKA will not authorise supply of Pomalidomide Krka to pharmacies that are not registered with KRKA.

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.

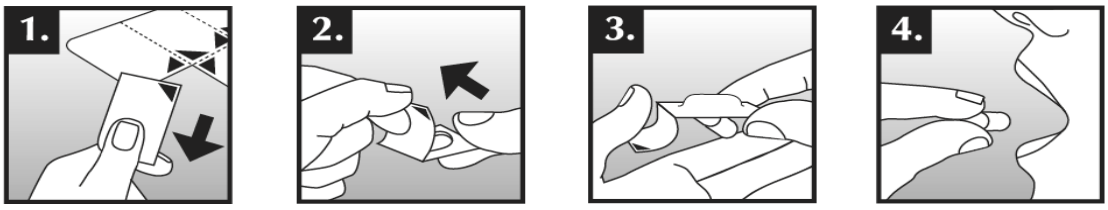
Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule.

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).

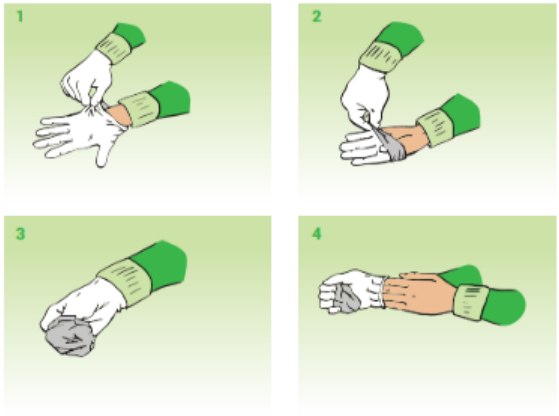
If the contents of the capsule are attached to the skin or mucous membranes

- 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
Thrombocytopenia • Platelet Count <25 x 10^9/L	Interrupt pomalidomide treatment, follow CBC weekly
• Platelet Count return to ≥50 x 10^9/L	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

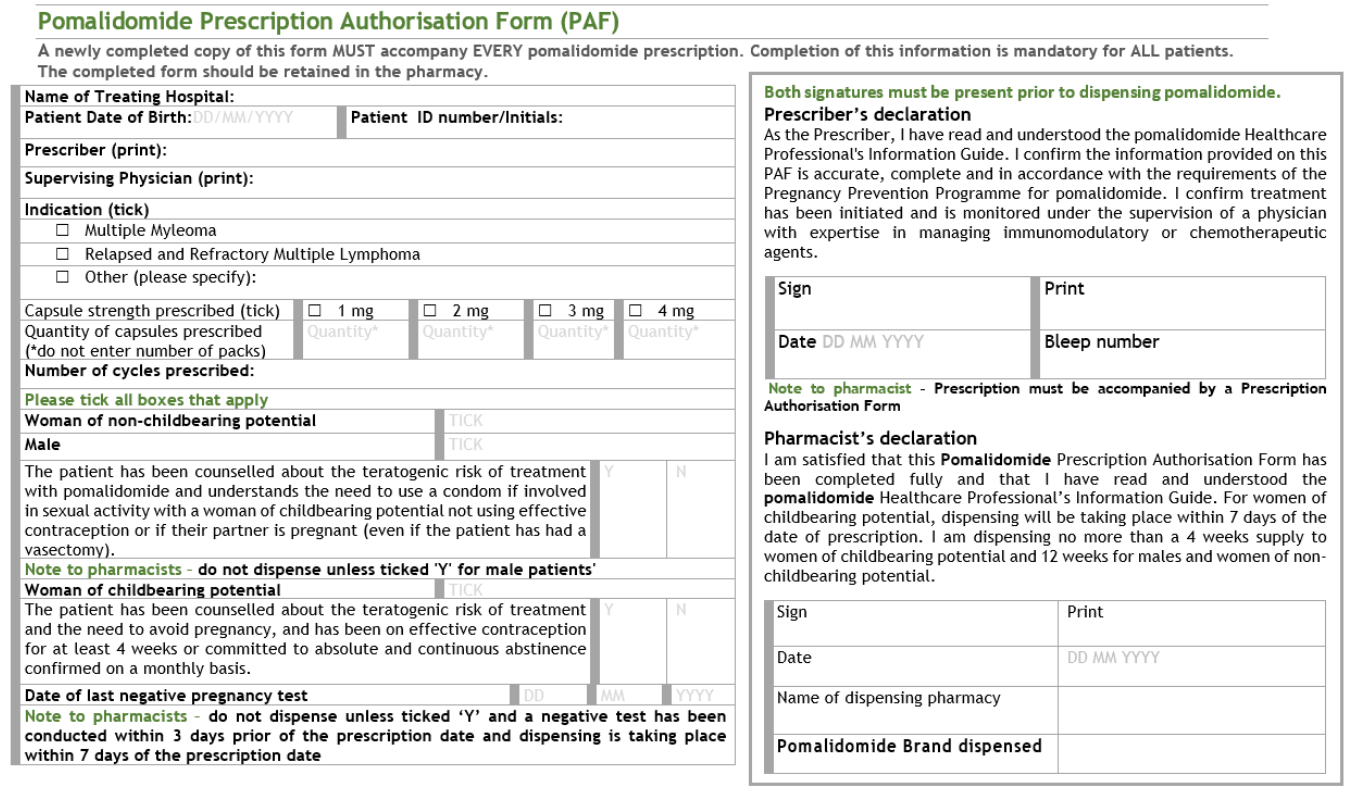
3. For orders through Uniphar, email 'Pomalidomide Krka (pomalidomide) Order Form' to KRKA on Info.IE@krka.biz

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

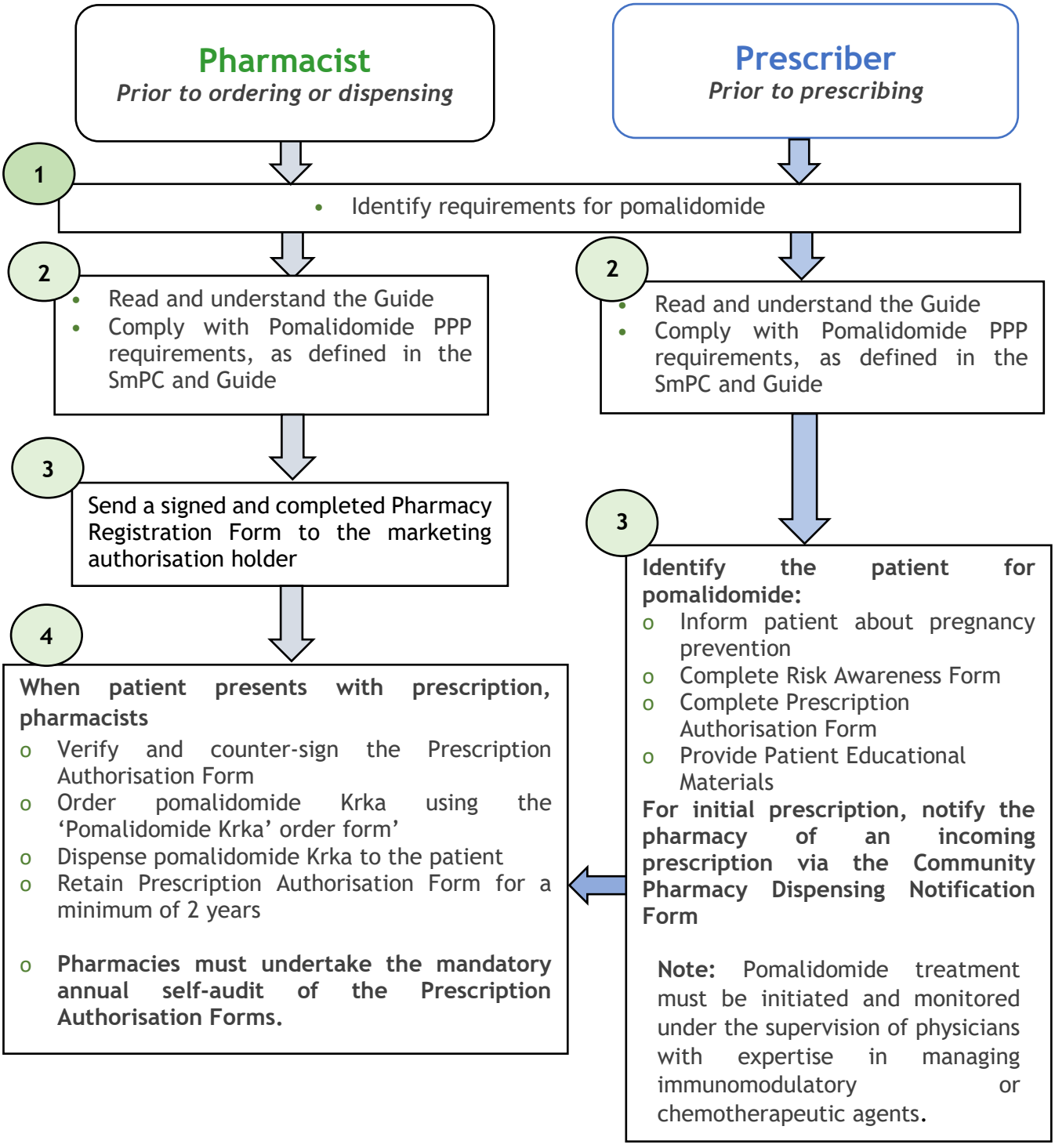
1. Print the full hospital name where the patient is treated.
2. Print the patient's date of birth and initials. If the middle initial is not known please use an underscore (e.g. J_S for John Smith). Do not provide confidential information (e.g. Patient Name and Hospital Number).
3. Print your name clearly.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

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POMALIDOMIDE

Pregnancy Prevention Programme Patient Guide

Information for Patients taking Pomalidomide

IRELAND

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet.

You can also report side effects directly via HPRA Pharmacovigilance at www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.
Side effects for KRKA products should also be reported to KRKA Medical Information on +353 1 413 3710 or pharmacovigilance.IE@krka.biz.

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

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

This Guide contains information about:

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

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

This Guide will help you understand what to do before, during and after taking pomalidomide.

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

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

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

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

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

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

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

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

Contents

Introduction

Pomalidomide is used to treat adults with a type of cancer called 'multiple myeloma'. Pomalidomide works in a number of different ways:

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

Pomalidomide is either used with:

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

Or

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

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

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

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

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

This Guide contains important information about the Pomalidomide Pregnancy Prevention Programme.

You must read the information carefully and before starting treatment you should:

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

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

Pomalidomide and Birth Defects

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

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

Pomalidomide and Other Possible Side Effects

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

Reporting of Side Effects

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

Special monitoring

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

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

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

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

Pregnancy Prevention Programme

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

- Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.
- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensure you are not pregnant during treatment. Before starting the treatment, you should ask your prescriber if you are able to become pregnant, even if you think this is unlikely
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity, you will have pregnancy tests under the supervision of your prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruptions and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation)
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a form documenting that you have been informed of the requirements of the Pregnancy Prevention Programme. Women of childbearing potential will be informed NOT to become pregnant throughout the duration of treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- If you are able to become pregnant, **unless you commit to absolute and continuous abstinence confirmed on a monthly basis**, you must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of the treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some

types of contraception are not recommended with pomalidomide. It is essential therefore that you discuss this with your prescriber. If necessary, your hospital team can refer you to a specialist for advice on contraception

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

Childbearing Potential Assessment

Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.

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

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

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant.

Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in this section

Women of Childbearing Potential

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects.

If pomalidomide is taken during pregnancy, a teratogenic effect is expected.

- **Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans**
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result.
- You should never share pomalidomide with anyone else
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment
- For additional information, please refer to the Package Leaflet
- You must never take pomalidomide if:
  - You are pregnant
  - Able to become pregnant, even if you are not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met
- You must stop treatment and inform your doctor straight away if you have heterosexual intercourse without using an effective method of contraception.

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

Contraception to Prevent Pregnancy

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

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

or

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

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

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

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

Not all types of contraception are suitable during pomalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

Males

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects.

If pomalidomide is taken during pregnancy, a teratogenic effect is expected.

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

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

Women of Non-Childbearing Potential

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects.

If pomalidomide is taken during pregnancy, a teratogenic effect is expected.

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

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

Pomalidomide Treatment in all patients

Before Starting Your Treatment

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

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

Before starting treatment, your prescriber will ask you to read and sign a form, which confirms that while taking pomalidomide:

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

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

Receiving Your Prescription

Your prescriber must complete a 'Prescription Authorisation Form' in addition to your prescription, which will be given to you to present at your nominated pharmacy or will be sent directly to your pharmacy each time you are prescribed pomalidomide. This form confirms that all of the Pregnancy Prevention Programme measures have been followed. Your pharmacist will review this documentation prior to ordering and dispensing your pomalidomide.

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

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

You will need to see your prescriber each time you need a repeat prescription.

Safety Measures During Treatment

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

You should never share pomalidomide with anyone else.

You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.

You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.

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

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

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

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

For additional information please refer to the Package Leaflet.

Taking other medicines

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

How to Take Your Medication

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

- Your prescriber will prescribe a dose of pomalidomide suited to you
- Always take pomalidomide exactly as your prescriber has told you. Check with your prescriber or pharmacist if you are not sure
- Your prescriber may adjust your dose depending on the result of blood tests and any side-effects you may experience
- Do not take more capsules than your prescriber has prescribed. If in doubt, ask your prescriber or pharmacist for advice
- Pomalidomide capsules should be swallowed whole, with a glass of water
- Pomalidomide can be taken at any time of day but it should be taken at approximately the same time each day
- Pomalidomide can be taken with or without food
- Do not break, open or chew the capsules. If powder from a broken pomalidomide capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water

How to store pomalidomide safely

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

End of Treatment Requirements

After completing your pomalidomide treatment, it is important that:

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

Additional advice for women of childbearing potential:

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

Additional advice for male patients:

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

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

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

Keep the blisters with the capsules in the original pack.

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

Healthcare professionals, caregivers and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of 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 family member and/or caregiver:

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

- Wash hands thoroughly with soap and water after removing gloves

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

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

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

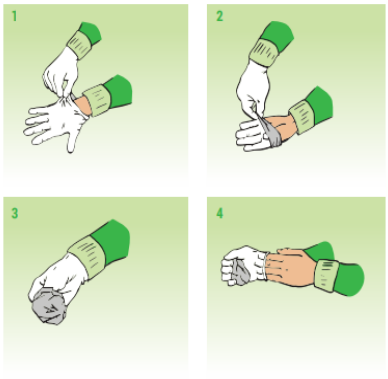
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of the powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water 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 prescriber and/or pharmacist immediately

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

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

Proper Technique for Removing Gloves:

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



Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

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Check List

Please use this check-list to confirm that you have understood all of the important information regarding your pomalidomide treatment.

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

Tick	Male Patients
	Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping pomalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
	Yes, I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping pomalidomide.

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

This Patient Guide is produced by KRKA

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

Information for Patients and Healthcare Professionals (HCP):

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

Women of childbearing potential must always use effective contraception

Women of childbearing potential must have pregnancy tests prior to starting treatment and every 4 weeks, prior to each prescription, to ensure that they are not pregnant, except in the case of confirmed tubal sterilisation

Male patients with pregnant partners or partners of childbearing potential not using effective contraception must always use condoms (even if man has had a vasectomy)

If a female patient or female partner of a male patient suspects they are pregnant, they must contact their prescriber immediately

You MUST tell your prescriber immediately if you experience any symptom that causes concern

For complete information on the side effects of pomalidomide, patients should read the Package Leaflet and HCP should read the Summary of Product Characteristics

Date of preparation of text: 2024 IE/ver1.0 HPRA Approved: 2024

Information for Healthcare Professionals:

Prescription Details

Has the patient received counselling?	Yes / No
Childbearing potential assessment	WCBP / WNCBP / Male
If the patient is a WCBP is she using effective contraception?	Yes / No
If the patient is male, is he using condoms, if required?:	Yes / No

WCBP: Women of childbearing potential; **WNCBP**: Women of non-childbearing potential

A completed Prescription Authorisation Form must accompany each prescription to confirm that the patient continues to use effective contraception (if required) and, in the case of a WCBP, is having a pregnancy test every 4 weeks before each prescription to ensure they are not pregnant.

Information for Healthcare Professionals (HCP):

Prescription Details

This patient is receiving pomalidomide for treatment of:

•
•
•
•

Date of preparation of text: 2024 IE/ver1.0 HPRA Approved: 2024

Emergency Contact Information

Emergency Prescriber Contact:

Telephone number during office hours:

Telephone number after office hours:

Further information is available in the patient Guide.

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Pomalidomide Risk Awareness Form

For All Patients
(Women of childbearing potential, Women of non-childbearing potential and Male)

IRELAND

Version 1.0

This Risk Awareness Form must be completed for each patient prior to the initiation of their pomalidomide treatment.

It is mandatory that all patients receive counselling and education to be made aware of the risks of pomalidomide. In particular, pomalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

The aim of the Risk Awareness Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse drug reactions associated with the use of pomalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Patients:
Women of childbearing potential: Complete Part A and Part B ***Men: Complete Part A and Part C***

Woman of non-childbearing potential: Complete Part A

Prescribers:
For women of childbearing potential complete Part D ***For male patients complete Part E***

The form should be retained with the patient's medical records, and a copy provided to the patient.

Warning: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.
If pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient details:

Patient First and Last Name	
Date of Birth	DD MM YYYY

Prescriber details

Prescriber First and Last Name	
Counselling Date	DD MM YYYY

PATIENT: PLEASE READ THOROUGHLY AND TICK THE ADJACENT BOX IF YOU AGREE WITH THE STATEMENT

PART A (all Patients-Women of childbearing potential, Women of non-childbearing potential and Male)	
• I understand that pomalidomide is expected to be harmful to an unborn baby and that severe birth defects may occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.	TICK
• I have read the pomalidomide patient guide and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	TICK
• I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	TICK
• I understand that I must return any unused capsules to my pharmacy at the end of my treatment.	TICK
• I understand that I cannot donate blood during treatment with pomalidomide, including dose interruptions and for at least 7 days after stopping treatment.	TICK
• I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	TICK
• I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each pomalidomide prescription, and that I must provide this to my pharmacy.	TICK
• I understand that the 'Prescription Authorisation Form' contains non-identifiable information about me, which will ensure pomalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder and the distributor for the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of Pomalidomide*.	TICK

PART B (only for Women of Childbearing Potential)	
• I understand that I must not take pomalidomide if I am pregnant or plan to become pregnant.	TICK
• I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	TICK
• I understand that if I need to change or stop my method of contraception, I will discuss this first with the presciber prescribing my contraception and the presciber prescribing my pomalidomide.	TICK
• I understand that that even if I have amenorrhoea I must comply with advice on contraception.	TICK
• I understand that before starting pomalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	TICK
• I understand that I must immediately stop taking pomalidomide and inform my prescriber if I become pregnant or suspect I am pregnant while taking this drug or within 4 weeks of treatment end, if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	TICK

PART C (only for Male Patients)	
• I have been told by my prescriber that I must NEVER have unprotected sexual contact with women who are pregnant or may become pregnant, whilst I am taking pomalidomide and for at least 7 days after stopping treatment.	TICK
• I understand that pomalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she does not use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop pomalidomide even if I have had a vasectomy.	TICK
• I understand that if my partner does become pregnant whilst I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide I should inform my prescriber immediately and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	TICK
• I understand that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after stopping treatment.	TICK
• I have been informed about effective contraceptive methods that my female partner can use.	TICK

Patient confirmation

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

Patient signature:	**Date:** DD MM YYYY

Statement of the interpreter (where appropriate)

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

Interpreter name and signature:	**Date:** DD MM YYYY

*****Your personal data is used solely for the purpose of entering you into the Pomalidomide Pregnancy Prevention Programme and is processed by the Marketing Authorisation Holder (MAH) of the pomalidomide product you receive, its third-party service providers and any worldwide Affiliates the MAH may have, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes. Third party service providers include, for example, the distributor of the pomalidomide product you receive.
Your pharmacist can confirm the details of the MAH for the pomalidomide product you are given and this will also be mentioned on the packaging and package leaflet. Queries on how your personal data will be processed can be directed to the MAH in question, by consulting their publicly available information (e.g., on their website) which details how they process your personal data and provides a contact point for any queries in relation to their use of your personal data.

PRESCRIBER: FOR WOMEN OF CHILDBEARING POTENTIAL (PART D) AND MALES (PART E)

PART D (For Women of Childbearing Potential)	
Did you inform your patient:	
1) Of the expected teratogenic risk to the unborn child and the need to avoid foetal exposure.	TICK
2) That if she is pregnant or plans to be, she must not take Pomalidomide.	TICK
3) Of the effective contraception she can use.	TICK
4) Of the need to avoid Pomalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment.	TICK
5) That if she needs to change or stop using her method of contraception she should inform: a. the prescriber prescribing her contraception that she is taking Pomalidomide. b. the prescriber prescribing Pomalidomide that she has stopped or changed her method of contraception.	TICK
6) Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment.	TICK
7) Of the need to stop Pomalidomide immediately upon suspicion of pregnancy.	TICK
8) Of the need to contact their prescriber immediately upon suspicion of pregnancy.	TICK
9) To not share the medicinal product with any other person.	TICK
10) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	TICK
11) That even if patient has amenorrhoea they must comply with advice on contraception.	TICK
12) Of hazards and necessary precautions associated with use of Pomalidomide.	TICK
13) That they should return the unused capsules to the pharmacist at the end of treatment.	TICK
14) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Pomalidomide.	TICK

Can you confirm your patient:		
Was referred to a contraceptive consultant, if required?	YES	NO
Is capable of complying with contraceptive measures?	YES	NO
Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	YES	NO
Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	YES	NO
Contraceptive referral for Women of Childbearing Potential		
• Contraceptive referral required	YES	NO
• Date Contraceptive referral made	DD MM YYYY	
• Date Contraceptive consultation conducted on	DD MM YYYY	
Pregnancy Prevention for Women of Childbearing Potential		
The patient has been established on one of the following for at least 4 weeks		
• Implant	TICK	
• Levonorgesterel-releasing intrauterine system (IUS)	TICK	
• Medroxyprogesterone acetate depot	TICK	
• Tubal sterilisation	TICK	
• Sexual intercourse with a vasectomised male partner only, vasectomy must be confirmed by two negative semen analyses	TICK	
• Ovulation inhibitory progesterone-only pills (e.g., desogestrel)	TICK	
• Committed to complete and absolute abstinence	TICK	
Pregnancy Test		
Date of last negative pregnancy test	DD MM YYYY	
POMALIDOMIDE TREATMENT CANNOT START UNTIL THE PATIENT HAS BEEN ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR ATLEAST 4 WEEKS, OR COMMITS TO COMPLETE AND CONTINUOUS ABSTINENCE, AND OBTAINS A NEGATIVE PREGNANCY TEST.		

PART E for Male Patients	
Did you inform your patient:	
1) Of the need to avoid foetal exposure.	TICK
2) To not share the medicinal product with any other person.	TICK
3) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	TICK
4) That they should return the unused capsules to the pharmacist at the end of treatment.	TICK
5) Of the effective contraceptive measures he or his female partner can use.	TICK
6) That Pomalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy) throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment.	TICK
7) That if his partner becomes pregnant, he should inform his treating prescriber immediately, his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	TICK
8) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	TICK
9) Of hazards and necessary precautions associated with use of Pomalidomide.	TICK
10) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Pomalidomide.	TICK

Can you confirm your patient:		
Is capable of complying with contraceptive measures?	YES	NO
Pregnancy Prevention for Male Patients		
The patient confirms that:		
• They will use a condom during intercourse with a woman of childbearing potential	TICK	
• Their female partner is using an effective contraceptive method	TICK	
• Their female partner is of non-childbearing potential	TICK	
• They are committed to complete and absolute abstinence	TICK	

Prescribers Confirmation

I confirm that:

- I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential.
- I have fully explained to the patient named above the importance of compliance with the requirements of the pomalidomide Pregnancy Prevention Programme.
- I will comply with all my obligations and responsibilities as the prescriber of pomalidomide.

Prescriber signature:	**Date:** DD MM YYYY

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	

Pomalidomide Community Pharmacy Dispensing Notification Form

1. To the prescriber

This is a notification form to advise the nominated community pharmacy that they will soon be receiving a High-Tech Prescription for pomalidomide for your patient. This will enable the community pharmacy to register with the Pomalidomide Pregnancy Prevention Programme and subsequently be able to order and dispense pomalidomide for your patient.

Please complete the Prescriber section below upon the first occasion that the patient is being prescribed pomalidomide and fax/email to the **Nominated Community Pharmacy** on the details below.

Prescriber Details (Please print)	
Date of Prescription:	Patient Identifier:
Full Name of Prescriber:	
Hospital Name and Address: (Please print)	Hospital stamp
Contact Phone Number:	

⇩

Fax/Email to Nominated Pharmacy	
Fax Number/Email:	
Nominated Pharmacy Name and Address: (Please print)	
Date Faxed/Email:	Time Faxed/Email:

2. To the Nominated Community Pharmacy

The prescriber named above has prescribed pomalidomide for their patient. The patient has nominated your pharmacy to dispense the prescription.

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

If you choose to dispense Pomalidomide Krka, you must register with KRKA, using the Pomalidomide Krka (pomalidomide) Pharmacy Registration Form (if you are not already registered). Please contact KRKA on +353 1 413 3710 and KRKA will forward you the relevant information.

If you have any questions regarding this form or require further information about pomalidomide please contact KRKA on +353 1 413 3710.

Pomalidomide Krka (pomalidomide) Pharmacy Registration Form

To be completed by the Chief/Superintendent Pharmacist or appointed deputy

Pharmacy name:	
Chief/Superintendent Pharmacist (or appointed deputy):	
Contact telephone number:	
Email:	**PSI Registration Number:**
Dispensing Pharmacy Address:	**Delivery Address (if different):**
Tel:	**Tel:**
Fax:	**Fax:**
Email:	**Email:**
Ordering Address (if different to delivery address):	

On behalf of . . . . . [pharmacy name], I agree to implement the following risk minimisation procedures when dealing with prescriptions for pomalidomide as specified by KRKA in the Pomalidomide Krka Healthcare Professional's Information Guide.

1	I have read and understood the Pomalidomide Krka Healthcare Professional's Information Guide.	TICK
2	All pharmacists who dispense Pomalidomide Krka will have read and understood the Pomalidomide Krka Healthcare Professional's Information Guide.	TICK
3	If supplied with Pomalidomide Krka, it will only be used for the purpose of dispensing the product by the Pregnancy Prevention Programme registered pharmacy to the patient.	TICK
4	Prescriptions for Pomalidomide Krka will be dispensed only if accompanied by a completed Pomalidomide Prescription Authorisation Form.	TICK
5	The pharmacist dispensing Pomalidomide Krka will check each prescription and Prescription Authorisation Form for completeness and countersign the authorisation form prior to dispensing.	TICK
6	Compliance with these procedures will be audited by the chief/superintendent pharmacist or appointed deputy at least annually. Audit results will be made available to KRKA so that their obligation to report to the regulatory agencies on the overall effectiveness of the programme can be met.	TICK
7	Pomalidomide Krka will be dispensed, checked and stored according to our standard documented procedures for oral anti-cancer medicines.	TICK
8	Dispensing will be limited to no more than a 4 week supply for women of childbearing potential, and 12 weeks for males and women of non-childbearing potential.	TICK
9	Dispensing of Pomalidomide Krka to women of childbearing potential should occur within 7 days of the prescription.	TICK
10	After dispensing, Pomalidomide Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years.	TICK
11	Pharmacies must undertake the **mandatory** annual self-audit of the PAFs.	TICK
12	I will notify KRKA of any change in contact details.	TICK

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

Signature:	
Print:	Date: DD MM YYYY

Email the completed form to KRKA on Info.IE@krka.biz
KRKA Pharma Dublin Limited, Office H, 1st Floor, Citywest Shopping Centre, Citywest Drive, Citywest, Dublin 24, Co.Dublin, D24 TYT9, Ireland

UDD ORDERS ONLY

Pomalidomide Krka (pomalidomide) Order Form Ireland

Orders cannot be processed unless this form is fully completed and signed. The completed Order Form should be emailed to United Drug Distribution (UDD), for the attention of UDD Customer Service **SpecialOrders@united-drug.com** or **Faxed to 01 463 2404**. Orders received **before 13:30 Monday-Friday** will be delivered on the customers' next available route as per customers' current delivery arrangements with United Drug Wholesale.

For queries about your order please email **SpecialOrders@united-drug.com** or **Telephone 01 463 2478**. Please ensure all data is recorded in Black or Blue ink. **Prescription Authorisation Forms and Prescriptions should not be sent to United Drug.**

Pharmacy Details (Please print)			
Ordered by: (Please print full name and position e.g.Irish registered pharmacists/technician)			
Pharmacy Name and Address: (Please print)			Pharmacy Stamp
Pharmacy Phone Number:			
Please indicate your nominated United Drug routine wholesaler: (Please tick)			UD Wholesale Account Number:
☐ Dublin	☐ Ballina	☐ Limerick	

Patient Details (Please print)	
Prescriber (Please print)	
Treating Hospital	
Indication	Patient date of birth DD MM YYYY

Male	TICK
Woman of childbearing potential (WCBP)	TICK
Woman of non-childbearing potential (WNCBP)	TICK

Dose of pomalidomide being prescribed	Date of prescription DD MM YYYY

Product Description	**Strength**	**Quantity required**
Pomalidomide capsules	2 mg	
Pomalidomide capsules	3 mg	
Pomalidomide capsules	4 mg	

Comments:

Is this the 1st, 2nd or 3rd dispensing of this prescription:			Total Supply Prescribed:			
☐ 1st	☐ 2nd	☐ 3rd	☐ 4-weeks	☐ 8-weeks	☐ 12-weeks	Other-specify:

I confirm that I am ordering on behalf of a registered pharmacy and that Pomalidomide Krka will be dispensed in accordance with the risk minimisation procedures for pomalidomide, as specified by KRKA in the Pomalidomide Krka Healthcare Professional's Information Guide.

I confirm that treatment lengths will be limited to a maximum of 4 weeks supply for women of childbearing potential and a maximum of 12 weeks for males and women of non-childbearing potential patients. For women of childbearing potential dispensing will be within 7 days of the date of prescription	Sign	Date DD MM YYYY
		Telephone
	Print:	

FOR INTERNAL USE ONLY			
Sales order:	Date: DD MM YYYY	Initials:	Tracker number:

UNIPHAR ORDERS ONLY

Pomalidomide Krka (pomalidomide) Order Form Ireland

Orders cannot be processed unless this form is fully completed and signed. The completed Order Form should be emailed to KRKA, for the attention of KRKA Customer Service **Info.IE@krka.biz**. Orders received **before 13:30 Monday-Friday** will be delivered on the customers' next available route as per customers' current delivery arrangements with Uniphar.

For queries about your order please email **Info.IE@krka.biz** or **Telephone 01 413 3710**. Please ensure all data is recorded in Black or Blue ink. **Prescription Authorisation Forms and Prescriptions should not be sent to KRKA.**

Pharmacy Details (Please print)							
Ordered by: (Please print full name and position e.g.Irish registered pharmacists/technician)							
Pharmacy Name and Address: (Please print)				Pharmacy Stamp			
Pharmacy Phone Number:							
Please indicate your nominated United Drug routine wholesaler: (Please tick)			Pharmacy GMS code:				
☐ Dublin	☐ Ballina	☐ Limerick					
Patient Details (Please print)							
Prescriber (Please print)							
Treating Hospital							
Indication			Patient date of birth DD MM YYYY				
Male						TICK	
Woman of childbearing potential (WCBP)						TICK	
Woman of non-childbearing potential (WNCBP)						TICK	
Dose of pomalidomide being prescribed			Date of prescription DD MM YYYY				
Product Description		**Strength**			**Quantity required**		
Pomalidomide capsules		2 mg					
Pomalidomide capsules		3 mg					
Pomalidomide capsules		4 mg					
Comments:							
Is this the 1st, 2nd or 3rd dispensing of this prescription:			Total Supply Prescribed:				
☐ 1st	☐ 2nd	☐ 3rd	☐ 4-weeks	☐ 8-weeks	☐ 12-weeks	Other-specify:	
I confirm that I am ordering on behalf of a registered pharmacy and that Pomalidomide Krka will be dispensed in accordance with the risk minimisation procedures for pomalidomide, as specified by KRKA in the Pomalidomide Krka Healthcare Professional's Information Guide.							

I confirm that treatment lengths will be limited to a maximum of 4 weeks supply for women of childbearing potential and a maximum of 12 weeks for males and women of non-childbearing potential patients. For women of childbearing potential dispensing will be within 7 days of the date of prescription	Sign	Date DD MM YYYY
		Telephone
	Print:	

FOR INTERNAL USE ONLY			
Sales order:	Date: DD MM YYYY	Initials:	Tracker number:

Pomalidomide Krka (pomalidomide) Pregnancy Reporting Form

This Pregnancy Reporting Form must be completed for each female patient or female partner of a male patient who experienced pregnancy during therapy with pomalidomide.
Pregnancy Reporting Form must be sent to KRKA, d.d., Novo mesto IMMEDIATELY. Please see contact details below.
KRKA, d.d., Novo mesto may contact you in order to gather additional information regarding foetal exposure to pomalidomide.

KRKA, d.d., Novo mesto
Telephone: +353 1 413 3710
Email: pharmacovigilance.IE@krka.biz

Reporter's Information			
Reporter's Name:		Reporter's Profession:	
Telephone number:		Email:	
Address:		Date of awareness: DD MM YYYY	
Patient and therapy Information			
Pregnant Woman's Initials (patient or female partner of a male patient receiving pomalidomide):		Date of Birth: DD MM YYYY	Age:
Please select one of the options below:			
☐ Pregnancy of Patient	☐ Pregnancy of Patient's Partner	☐ Exposure of a Pregnant Female	
Drug Name:			
Batch Number:	Shelf life:	Daily dosage:	Frequency:
Date of First Dose: DD MM YYYY		Date of Last Dose: DD MM YYYY	
Indication:			

Pregnancy test	**Reference Range:**	**Date** DD MM YYYY
☐ Urine Qualitative		
☐ Serum Quantitative		

Date of Last Menstrual Period:		
Female is Currently: ……. weeks pregnant	No Longer Pregnant	Unknown
Female has elected to	Carry Pregnancy to Term	Estimated Delivery Date: DD MM YYYY
	Terminate Pregnancy	Date Performed or Pending: DD MM YYYY

Patient's Prescriber's Information:	
Prescriber Name:	Date: DD MM YYYY
Address:	Email:
Phone number:	Fax:

Name of the person completing this form	**Signature**	**Date** DD MM YYYY

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

Prenatal Information	
Date of Last Menstrual Period: DD MM YYYY	Estimated Delivery Date: DD MM YYYY

Pregnancy test		
☐ Urine Qualitative	Reference Range:	Date: DD MM YYYY
☐ Serum Quantitative	Reference Range:	Date: DD MM YYYY

Past Obstetric History						
Year of Pregnancy	**Outcome**				**Gestational Age**	**Type of Delivery**
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		

Birth defects			
Was there any birth defect from any pregnancy?	☐ YES	☐ NO	☐ UNKNOWN
Is there any family history of any congenital abnormality abstinence?	☐ YES	☐ NO	☐ UNKNOWN
If yes to either of these questions, please provide details below:			

Background Information on Reason for Pregnancy				
Maternal Past Medical History				
Condition	**From Date**	**To Date**	**Treatment**	**Outcome**
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		

Maternal Current Medical Conditions		
Condition	**From Date**	**Treatment**
	DD MM YYYY	
	DD MM YYYY	
	DD MM YYYY	
	DD MM YYYY	
	DD MM YYYY	
	DD MM YYYY	
	DD MM YYYY	
	DD MM YYYY	

Maternal Social History			
Alcohol	☐ YES	☐ NO	If yes, amount/units per day:
Tobacco	☐ YES	☐ NO	If yes, amount per day:
IV or recreational drug use	☐ YES	☐ NO	If yes, provide details:

Maternal medication during pregnancy and in 4 weeks before pregnancy (including herbal, alternative and over the counter medicines and dietary supplements)			
Medication/Treatment	**Start date**	**Stop date/ Continuing**	**Indication**
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	

Name of person completing this form	**Signature**	**Date** DD MM YYYY

Data Privacy Notice

Your personal data (aggregated anonymised patient limited data e.g., patient initials, date of birth) will be processed by KRKA d.d. Novo mesto, as Marketing Authorisation Holder (MAH) of pharmaceutical products and its worldwide affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes.

To conduct risk management program activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

KRKA may disclose your personal information to regulatory authorities, affiliates of the KRKA Group, service providers or other collaborators. Some of these entities may be located outside of the EU. KRKA will take appropriate measures, such as implementing standard data protection clauses adopted by the European Commission, to ensure that your personal information will be kept secure in accordance with applicable data protection law. KRKA will only retain your personal data for the length of time required by law.

Under applicable law, you may have the right to access and verify your personal information held by KRKA, receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing. If you wish to exercise those rights, you can contact our data protection officer at Info.IE@krka.biz

Reporter's Signature (required)	**Date** DD MM YYYY

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

Pomalidomide Krka (pomalidomide) Event-Specific Questionnaire for HCP - Pregnancy Outcome Form

This form must be returned to KRKA, d.d., Novo mesto; Telephone: +353 1 413 3710; Email: pharmacovigilance.IE@krka.biz

Reporter's Information					
Reporter's Name:			Email:		
Reporter's Profession:			Telephone number:		
Address:			Fax number:		
Patients Information					
Patient's ID:	Date of birth: DD MM YYYY		Ethnicity:		
			☐ White	☐ African-Caribbean	☐ Other, specify:
Partners of patients Information					
☐ Not applicable	Ethinicity:		☐ White	☐ African-Caribbean	☐ Other, specify:
Pregnancy Outcome					
Date of delivery:	DD MM YYYY		Gestation age of delivery:	DD MM YYYY	
Normal	☐ No	☐ Yes			
C-section	☐ No	☐ Yes			
Induced	☐ No	☐ Yes			
Ectopic pregnancy	☐ No	☐ Yes			
Elective termination	☐ No	☐ Yes	**Date:** DD MM YYYY		
Spontaneous abortion (≤20 weeks)	☐ No	☐ Yes	**Weeks from LMP:**		
Foetal death/stillbirth (>20 weeks)	☐ No	☐ Yes			
Were the products of conception examined?	☐ No	☐ Yes	If yes, was the foetus normal? If no describe below/Unknown		
Obstetrics Information					
Complications during pregnancy	☐ No	☐ Yes	If yes, please specify:		
Complications during labour/delivery	☐ No	☐ Yes	If yes, please specify:		
Post-partum maternal complications	☐ No	☐ Yes	If yes, please specify:		
Foetal Outcome					
Live normal infant	☐ No	☐ Yes			
Foetal distress	☐ No	☐ Yes			
Intra-uterine growth retardation	☐ No	☐ Yes			
Neonatal complication	☐ No	☐ Yes	If yes, please specify:		
Birth defect noted?	☐ No	☐ Yes	If yes, please specify:		
Sex	☐ Male	☐ Female	**Birth weight**:…….lbs…….oz or…….Kg **Length**……inchs or ……..cm		
Apgar score	1 min:…… 5 min:……. 10 min:……		☐ Unknown		

Signature of the person completing this form (required)	**Date** DD MM YYYY

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Reporter's Signature (required)	**Date** DD MM YYYY

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

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