Lenalidomide Krka (lenalidomide)

Healthcare Professionals Information Pack

IRELAND

Version 02

Important Safety Information:

Healthcare Professionals involved in the prescribing or dispensing of lenalidomide must read and understand the information relevant to prescriber and dispensing pharmacy contained within this pack

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

IE/ver2.0; Date of texts preparation: February 2024; HPRA Approved: February 2024

Lenalidomide Krka (lenalidomide)

Healthcare Professional's Information Pack

IRELAND

This pack contains the information and materials needed for the prescribing and dispensing of lenalidomide, 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 the content relevant to prescriber and dispensing pharmacy detailed in this pack before prescribing or dispensing lenalidomide for any patient

This pack contains the following contents:

Information for healthcare professionals involved in the prescribing or dispensing of lenalidomide

Lenalidomide Krka (lenalidomide)

Healthcare Professionals Information Guide

IRELAND

Version 02

Important Safety Information:
Healthcare Professionals involved in the prescribing or dispensing of lenalidomide must read and understand the information contained within this Guide

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

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

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

IE/ver2.0; Date of texts preparation: February 2024; HPRA Approved: February 2024

Lenalidomide Krka (lenalidomide)

Pregnancy Prevention Programme

and

Information for Healthcare Professionals

Prescribing or Dispensing Lenalidomide

IRELAND

This Guide contains the information and materials needed for the prescribing and dispensing of lenalidomide, including information about the Pregnancy Prevention Programme (PPP) and important safety information. This Guide will help you understand these problems and make sure you know what to do before prescribing and dispensing lenalidomide.

Lenalidomide Krka Pregnancy Prevention Programme

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby. This Programme is designed to make sure that unborn babies are not exposed to lenalidomide. It will provide you with information about how to follow the programme and explain your responsibilities.

It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals (HCP) ensure that they have read and understood the HCP Information Guide before prescribing or dispensing lenalidomide for any patient.

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 lenalidomide and that they have provided written confirmation on the Treatment Initiation Form, before starting treatment.

For full information regarding the requirements of the PPP, as well as safety information, side effects and recommended precautions please also refer to the Lenalidomide Krka Summary of Product Characteristics (SmPC), which is available at the following websites: www.hpra.ie/www.ema.europa.eu.

Contents

Introduction

Lenalidomide – Risk of Teratogenicity

Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. An embryofoetal development study has been conducted in monkeys administered lenalidomide at doses up to 4 mg/kg/day. Findings from this study showed that lenalidomide produced external malformations (short limbs, bent fingers/toes, wrist and/or tail, supernumerary or absent fingers/toes) in the offspring of female monkeys who received the drug during pregnancy. Thalidomide produced similar types of malformations in the same study.

If lenalidomide is taken during pregnancy, a teratogenic effect can be expected. Therefore, lenalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met.

Licensed Indication

Lenalidomide is an immunomodulating medicinal poduct.

- Lenalidomide as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed **multiple myeloma** who have undergone autologous stem cell transplantation.

AND

- Lenalidomide as combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone is indicated for the treatment of adult patients with previously untreated **multiple myeloma** who are not eligible for transplant.

AND

- Lenalidomide in combination with dexamethasone is indicated for the treatment of **multiple myeloma** in adult patients who have received at least one prior therapy.

AND

- Lenalidomide as monotherapy is indicated for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk **myelodysplastic syndromes** associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

AND

- Lenalidomide as monotherapy is indicated for the treatment of adult patients with relapsed or refractory **mantle cell lymphoma**.

AND

- Lenalidomide in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated **follicular lymphoma** (Grade 1 – 3a).

When lenalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior initiation of treatment.

Posology

Newly Diagnosed Multiple Myeloma

Lenalidomide maintenance in patients who have undergone autologous stem cell transplantation (ASCT)

The recommended starting dose is lenalidomide 10 mg orally once daily continuously (on Days 1 to 28 of repeated 28-day cycles) given until disease progression or intolerance. After 3 cycles of lenalidomide maintenance, the dose can be increased to 15 mg orally once daily if tolerated. Dose reduction steps are provided in Section 4.2 of the SmPC.

Lenalidomide in combination with dexamethasone until disease progression in patients who are not eligible for transplant

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of repeated 28-day cycles. Patients may continue lenalidomide and dexamethasone therapy until disease progression or intolerance. Dose reduction steps are provided in Section 4.2 of the SmPC.

Lenalidomide in combination with bortezomib and dexamethasone followed by lenalidomide and dexamethasone until disease progression in patients who are not eligible for transplant

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 14 of each 21-day cycle in combination with bortezomib and dexamethasone. The recommended dose of bortezomib is 1.3 mg/m^2 body surface area subcutaneously twice weekly on Days 1, 4, 8 and 11 of each 21-day treatment cycles. Up to eight 21-day treatment cycles (24 weeks of initial treatment) are

recommended. Continue lenalidomide 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles in combination with dexamethasone. Treatment should be continued until disease progression or unacceptable toxicity. Dose reduction steps are provided in Section 4.2 of the SmPC.

Lenalidomide in combination with melphalan and prednisone followed by lenalidomide maintenance in patients who are not eligible for transplant

The recommended starting dose of lenalidomide is 10 mg/day orally on Days 1-21 of repeated 28-day cycles for up to 9 cycles, melphalan 0.18 mg/kg orally on Days 1-4 of repeated 28 day cycles, prednisone 2 mg/kg orally on Days 1-4 of repeated 28-day cycles. Patients who complete 9 cycles or who are unable to complete the combination therapy due to intolerance are treated with lenalidomide alone as follows: 10 mg/day orally on Days 1-21 of repeated 28-day cycles given until disease progression. Dose reduction steps are provided in Section 4.2 of the SmPC.

Multiple Myeloma patients with at least one prior therapy

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1-21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on Days 1-4, 9-12, and 17-20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg once daily on days 1-4 every 28 days. Dosing is continued or modified based upon clinical and laboratory findings. Prescribing physicians should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient. Dose reduction steps are provided in Section 4.2 of the SmPC.

Myelodysplastic Syndromes

The recommended starting dose of lenalidomide is 10 mg orally once daily on Days 1 to 21 of repeated 28-day cycles. Dose reduction steps are provided in Section 4.2 of the SmPC.

Mantle Cell Lymphoma

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles. Dose reduction steps are provided in Section 4.2 of the SmPC.

Follicular Lymphoma

The recommended starting dose of lenalidomide is 20 mg orally once daily on Days 1 to 21 of repeated 28-day cycles for up to 12 cycles of treatment. The recommended starting dose of rituximab is 375 mg/m^2 intravenously every week in Cycle 1 (Days 1, 8, 15, and 22) and Day 1 of every 28-day cycle for Cycles 2 through 5. Dose reduction steps are provided in Section 4.2 of the SmPC.

Lenalidomide Krka Pregnancy Prevention Programme (PPP)

- It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals read and understand this Guide before prescribing or dispensing Lenalidomide Krka for any patient
- All men and all women of childbearing potential should undergo, at treatment initiation, counselling regarding the need to avoid foetal exposure to lenalidomide during pregnancy. Treatment Initiation Forms are available for this purpose. The patient should receive a copy of the Treatment Initiation Form when completed
- The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is illustrated in the **Algorithm below**
- Patients should be capable of complying with the requirements of safe use of lenalidomide
- Patients must be provided with appropriate Patient Educational Guide (Patient Guide) and Patient Pocket Information Card

All of the Lenalidomide Krka Pregnancy Prevention Programme materials are available electronically on the website www.hpra.ie (enter 'Lenalidomide Krka' under 'Find a Medicine' and click 'EdM' under the 'Documents' column). Additional hard copies can be obtained from KRKA by using the contact details provided in this Guide.

You must ensure that your patient fully understands what you have told them about lenalidomide before starting the treatment.

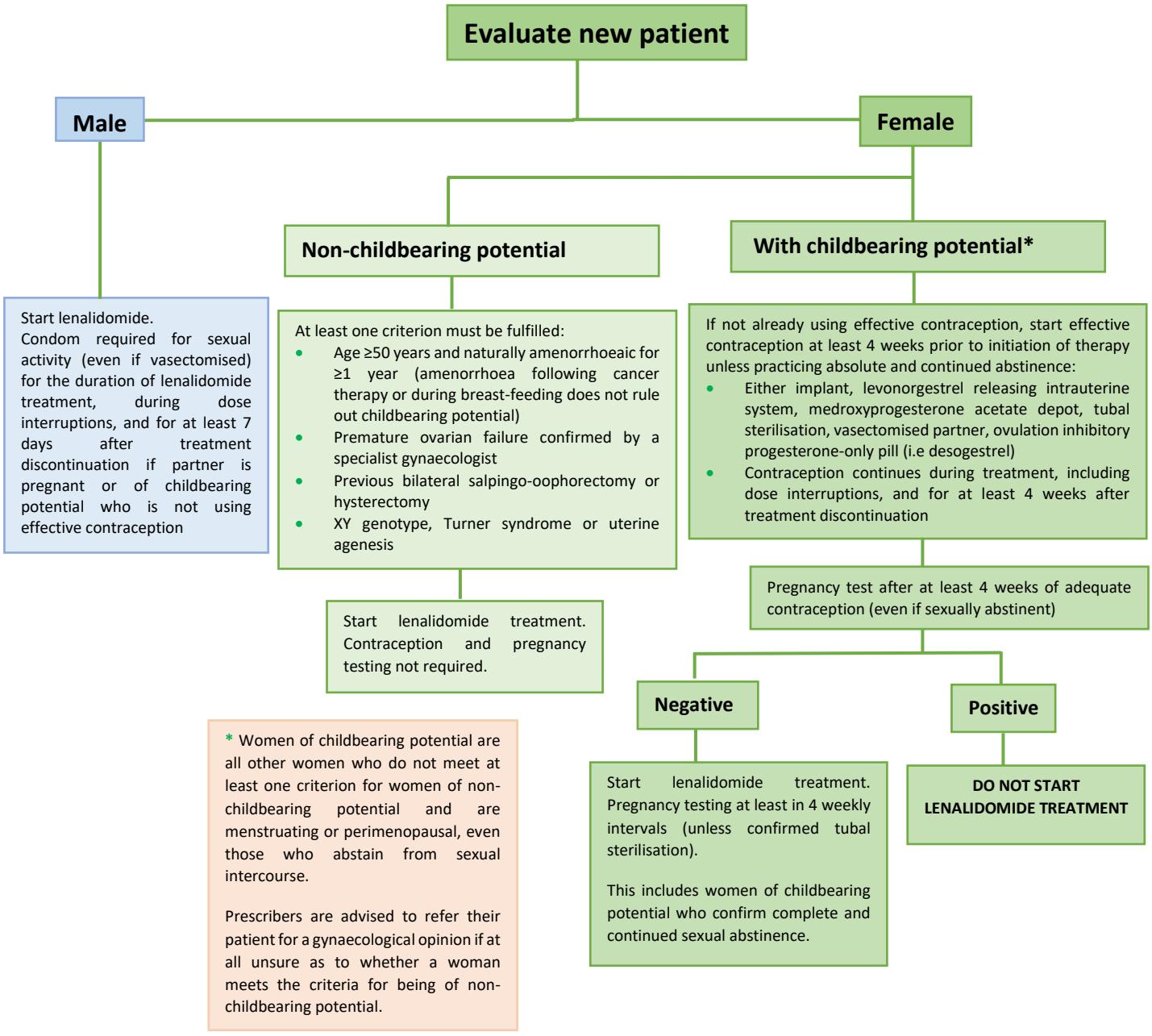
In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of Lenalidomide Krka will only be allowed from pharmacies registered with KRKA. KRKA will not authorise supply of lenalidomide to pharmacies that are not registered with KRKA.

The following are core requirements of the Pregnancy Prevention Programme (PPP):

- A controlled distribution system
- All healthcare professionals who intend to prescribe or dispense lenalidomide must be provided with Lenalidomide Krka Healthcare Professional's Information Guide and other relevant materials as needed

- All healthcare professionals prescribing or dispensing lenalidomide must read and understand the Healthcare Professional's Information Guide
- Every prescription for lenalidomide must be accompanied by a Prescription Authorisation Form, which must be completed and signed by the prescriber and checked and counter-signed by the pharmacy
- All pharmacies who dispense Lenalidomide Krka must implement risk minimisation by registering with the KRKA Pregnancy Prevention Programme and in accordance with the measures described in this Guide

Description of Pregnancy Prevention Program and Patient Evaluation 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 lenalidomide 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 lenalidomide, 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 lenalidomide 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 lenalidomide 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 lenalidomide in combination therapy, and to a lesser extent in patients with multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma taking lenalidomide monotherapy, 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 levonorgestrel-releasing intrauterine systems 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 lenalidomide, she must stop treatment immediately and inform her prescriber.

Requirements in the event of a suspected pregnancy while on treatment with Lenalidomide 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 lenalidomide, foetal exposure should be avoided.
- Inform your patient about the effective contraceptive methods that his female partner can use.
- Lenalidomide 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 lenalidomide or shortly after he has stopped taking lenalidomide 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 lenalidomide.

If the partner of a male taking Lenalidomide 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.

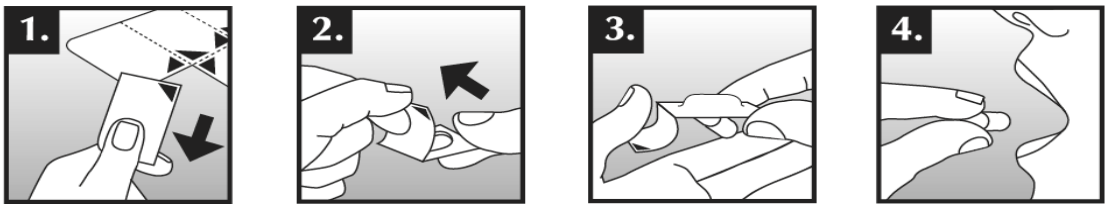
Points to consider for handling the medicinal product: for patients, healthcare professionals and caregivers

Taking this medicine

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

To remove the Lenalidomide 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 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).

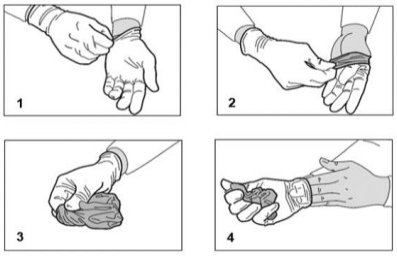
If the contents of the capsule are attached to the skin or mucous membranes

- 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

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure 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.

- 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



Blood donations

Patients should not donate blood during treatment, including during dose interruptions and for at least 7 days after stopping of treatment with lenalidomide.

Prescribing and Dispensing Lenalidomide

Lenalidomide 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 lenalidomide 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 lenalidomide in accordance with the measures described in this Guide and the SmPC

- Obtain written confirmation (using the Treatment Initiation 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 lenalidomide 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 lenalidomide. The lenalidomide 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 lenalidomide.

Subsequent Prescriptions

- Before issuing subsequent prescriptions, you must:
  - Ensure your patient continues to understand the risks of lenalidomide therapy.
  - Ensure that your patient is continuing to use the appropriate contraceptive measures, if relevant.
- Provide a 'Prescription Authorisation Form' to the patient or submit electronically to the pharmacy with each lenalidomide prescription.

Prescribers wishing to prescribe Lenalidomide Krka must read the Healthcare Professional's Information Guide provided by KRKA. This is available in hardcopy from KRKA or electronically via the website www.hpra.ie.

Prescription Authorisation Form

Every prescription for lenalidomide 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 lenalidomide 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 lenalidomide 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 Treatment Initiation 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
- The information provided on this Prescription Authorisation Form is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme for lenalidomide
- 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 lenalidomide. The patient must return to their prescriber for every repeat prescription of lenalidomide.

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.

Dispensing Lenalidomide

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

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

Lenalidomide 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 Notification and Registration

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

Ordering of lenalidomide

The pharmacy must be registered with KRKA to order Lenalidomide Krka. To order Lenalidomide Krka the pharmacy must use a specific Lenalidomide Krka (lenalidomide) 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 lenalidomide.

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 lenalidomide 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 lenalidomide 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 lenalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription.

For all patients

- Please ensure that you dispense lenalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles
- Instruct patients to return any unused lenalidomide capsules to the pharmacy. Pharmacies must accept any unused lenalidomide 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 lenalidomide.

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

The terms of the Lenalidomide 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 lenalidomide 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 Lenalidomide 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 Lenalidomide

The following section contains advice to Healthcare Professionals about how to minimise the main risks associated with the use of lenalidomide. Please refer also to the SmPC (Section 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects).

Tumour flare reaction in mantle cell lymphoma and follicular lymphoma patients

Tumour flare reaction (TFR) has commonly been observed in patients with mantle cell lymphoma, who were treated with lenalidomide or follicular lymphoma treated with lenalidomide and rituximab. The patients at risk of TFR are those with high tumour burden prior to treatment. Caution should be practiced when introducing these patients to lenalidomide. These patients should be monitored closely, especially during the first cycle or dose-escalation and appropriate precautions taken.

At the physician's discretion, lenalidomide may be continued in patients with Grade 1 or 2 TFR without interruption or modification. At the physician's discretion, therapy with non-steroidal anti-inflammatory drugs (NSAIDs), limited duration corticosteroids, and/or narcotic analgesics may be administered. In patients with Grade 3 or 4 TFR, withhold treatment with lenalidomide and initiate therapy with NSAIDs, corticosteroids and/or narcotic analgesics. When TFR resolves to ≤ Grade 1, restart lenalidomide treatment at the same dose level for the rest of the cycle.

Patients may be treated for management of symptoms per the guidance for treatment of Grade 1 and 2 TFR.

Second primary malignancies

The risk of occurrence of Second Primary Malignancies (SPM) must be taken into account before initiating treatment with lenalidomide either in combination with melphalan or immediately following high dose melphalan and ASCT. Prescribers should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

An increase of SPM has been observed in clinical trials in previously treated myeloma patients with lenalidomide/dexamethasone compared to controls, mainly comprising of basal cell or squamous cell skin cancers.

Cases of haematological SPM such as acute myeloid leukaemia (AML) have been observed in clinical trials of newly diagnosed multiple myeloma in patients taking lenalidomide in combination with melphalan or immediately following high dose melphalan and ASCT (HDM/ASCT; see Section 4.4 of the SmPC). This increase was not observed in clinical trials of newly diagnosed multiple myeloma in patients taking lenalidomide in combination with dexamethasone compared to thalidomide in combination with melphalan and prednisone.

Progression to acute myeloid leukaemia in low- and int-1-risk MDS patients

Baseline variables including complex cytogenetics and TP53 mutation are associated with progression to AML in subjects who are transfusion dependent and have a Del (5q) abnormality (see Section 4.4 of the SmPC).

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

The safe use of lenalidomide is of paramount importance.
Adverse Events (and cases of Suspected or Confirmed Pregnancy or Foetal Exposure) should be reported to the manufacturer. Adverse Event Report Forms and Pregnancy Reporting Forms for Lenalidomide Krka should be forwarded to KRKA Medical Information (Telephone❫: +353 1 413 3710; Email✉: pharmacovigilance.IE@krka.biz)

Suspected Adverse reaction reports can also be reported via the HPRA Pharmacovigilance website: www.hpra.ie.

Prescribers Guide to Prescribing Lenalidomide Schematic

In order to initiate therapy with lenalidomide:

1. Read the Lenalidomide 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 Treatment Initiation Form and provide patient with a copy.

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

For the FIRST prescription of lenalidomide Follow steps 1 to 4

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

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

For SUBSEQUENT prescriptions of lenalidomide Follow steps 3 to 4

3. Prescribe lenalidomide 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 lenalidomide must be accompanied by a **Lenalidomide Prescription Authorisation Form.**

Pharmacists Guide to Dispensing Lenalidomide Schematic

In order to dispense Lenalidomide 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 lenalidomide.

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 **'Lenalidomide Krka (lenalidomide) Order Form'.**
5. Fax/Email **'Lenalidomide Krka (lenalidomide) 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.
6. For orders through Uniphar, email 'Lenalidomide Krka (lenalidomide) Order Form' to KRKA on Info.IE@krka.biz

You are a Community Pharmacy that has previously registered with KRKA

1. Complete a '**Lenalidomide Krka (lenalidomide) Order Form'**.
2. Fax/Email **'Lenalidomide Krka (lenalidomide) 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'Lenalidomide Krka (lenalidomide) 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 lenalidomide from High Technology Prescription

A Guide to Completing the Prescription Authorisation Form (PAF)

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

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 for which lenalidomide is being prescribed – this is for the purposes of monitoring off-label use.
6. Enter the capsule strength, quantity of capsules prescribed and the number of cycles precribed.
7. Complete this section appropriately to indicate that counselling has occurred 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 included lenalidomide 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 that:
   - counselling and contraceptive measures have been confirmed by the prescriber as appropriate
   - indication, capsule strength, quantity or capsules and number of cycles prescribed have been provided
   - for women of childbearing potential a negative pregnancy test date is provided and is within 3 days of the prescription date

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.
   - dispense only a maximum of 4 weeks supply for Women of childbearing potential at any one time
   - dispense only a maximum of 12 weeks supply for Males and Women of non-childbearing potential

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

Further information and materials are available from KRKA

Phone number✆: +353 1 413 3710

Email✉: Info.IE@krka.biz **or** pharmacovigilance.IE@krka.biz

Lenalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY lenalidomide 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:						
Indication (tick)						
☐ Multiple Myeloma						
☐ Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality						
☐ Mantle Cell Lymphoma relapsed and/or refactory						
☐ Follicular Lymphoma						
☐ Other (please specify) _____						
Capsule strength prescribed (tick) / Quantity of capsules prescribed(*do not enter number of packs)						
☐ 2.5 mg	☐ 5 mg	☐ 7.5 mg	☐ 10 mg	☐ 15 mg	☐ 20 mg	☐ 25 mg
Quantity*	Quantity*	Quantity*	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 lenalidomide 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 lenalidomide.

Prescriber's declaration

As the Prescriber, I have read and understood the lenalidomide 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 lenalidomide. 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

Pharmacist's declaration

I am satisfied that this **Lenalidomide** Prescription Authorisation Form has been completed fully and that I have read and understood the **Lenalidomide** 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	
Lenalidomide Brand dispensed	

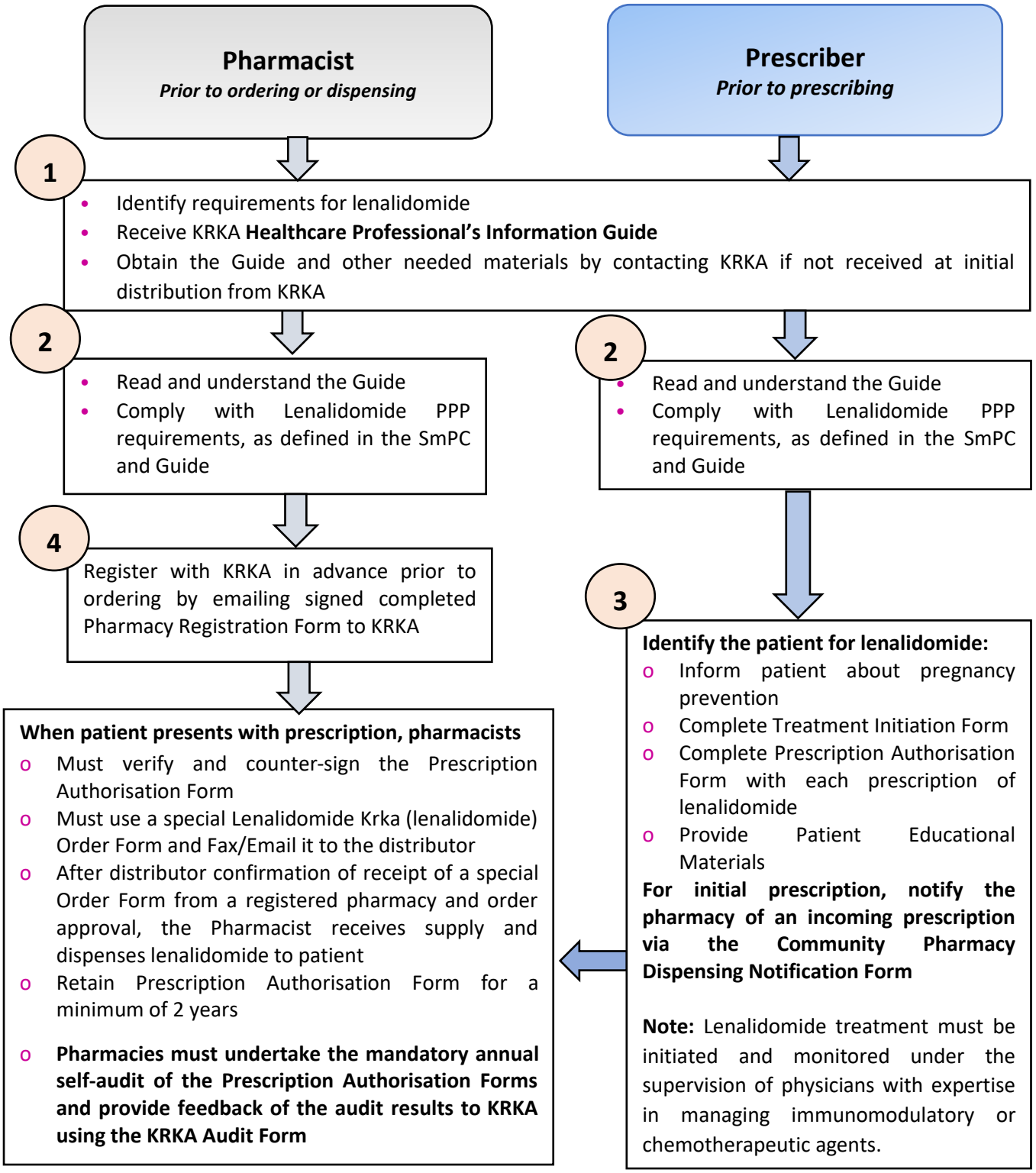
Mandatory Lenalidomide Krka Order Forms

Following discussions with the Health Products Regulatory Authority (HPRA), compliance with the PPP will also be monitored through Lenalidomide Krka (lenalidomide) Order Forms to enable additional exposure data to be captured.

All information required to complete these Order Forms can be found on the Prescription Authorisation Form. Order Forms will be forwarded by United Drug Distribution (UDD) to KRKA who will then compile anonymised and aggregated data reports to provide to the HPRA on a annual basis.

KRKA will keep the Order Forms for orders through Uniphar and will provide Uniphar with a copy.

Prescribing and Dispensing of Lenalidomide Schematic



Contact Details

Risk Management:

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

KRKA Pharma Dublin Limited
Office H, 1st Floor
Citywest Shopping Centre
Citywest Drive, Citywest
Dublin 24, Co. Dublin
D24 TYT9
Ireland

IE/ver2.0; Date of texts preparation: February 2024; HPRA Approved: February 2024

LENALIDOMIDE

Pregnancy Prevention Programme Patient Guide

Information for Patients taking Lenalidomide

IRELAND

IE/ver2.0; Date of texts preparation: February 2024; HPRA Approved: February 2024

This guide contains information about:

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

LENALIDOMIDE Pregnancy Prevention Programme: This Programme is designed to ensure that unborn babies are not exposed to lenalidomide. 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 lenalidomide.

This guide will not give you information about multiple myeloma, myelodysplastic syndrome, mantle cell lymphoma or follicular lymphoma. You should ask your prescriber if you have any questions.

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

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

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

Lenalidomide 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 lenalidomide capsules.

This guide also contains important information about the requirement to avoid blood donation during treatment, the safe handling of lenalidomide and the safe

Contents

Introduction

Lenalidomide works by affecting the body's immune system and directly attacking the cancer.

It 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

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

Lenalidomide is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects. Precautions must be taken to avoid exposure to lenalidomide in an unborn baby.

This guide contains important information about the lenalidomide Pregnancy Prevention Programme.

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

- Understand the risks of lenalidomide 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 lenalidomide
- Understand the guidelines for taking lenalidomide 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 lenalidomide treatment and specific instructions that you must follow
- Please make sure that you understand what your prescriber has told you before starting lenalidomide

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

Lenalidomide and Birth Defects

All medicines can cause unwanted effects or ‘side effects’. An extremely important side effect of lenalidomide 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 lenalidomide must never be taken by:

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

Lenalidomide and Other Possible Side Effects

Like all medicines, lenalidomide 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 lenalidomide 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 lenalidomide you will have regular blood tests. This is because lenalidomide 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

Your prescriber will also monitor how well your kidneys are working.
Your prescriber may adjust your dose of lenalidomide 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 **lenalidomide is expected to be harmful to an unborn child.**

- Before starting lenalidomide 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 lenalidomide, 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 lenalidomide and for at least 4 weeks after stopping lenalidomide.
- 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

lenalidomide. 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 lenalidomide or in the 4 weeks after stopping, you must stop lenalidomide 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 lenalidomide if you are pregnant, think you may be pregnant or are planning to become pregnant, as lenalidomide is expected to be harmful to an unborn child.

Childbearing Potential Assessment

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

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

- **Lenalidomide 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 lenalidomide, your prescriber will complete a Treatment Initiation Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 4 weeks after stopping lenalidomide
- You should never share lenalidomide 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 lenalidomide 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

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

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

OR

- Agree you will not engage in sexual activity with a male partner starting atleast 4 weeks before lenalidomide treatment, during lenalidomide treatment, during any

breaks in lenalidomide treatment and for at least 4 weeks after stopping lenalidomide treatment. You will be asked to confirm this every month.

- Inform the prescriber of your contraception that you are on lenalidomide.
- You should start your lenalidomide treatment as soon as possible after having a negative pregnancy test result and having received lenalidomide.
- Not all types of contraception are suitable during lenalidomide 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.

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

Males

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

- Lenalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans
- 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 lenalidomide, your prescriber will complete a Treatment Initiation Form documenting that you have been informed of the requirement for your partner NOT to become pregnant throughout the duration of your treatment with lenalidomide and for at least 7 days after you stop lenalidomide
- You should never share lenalidomide 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
- Lenalidomide 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 lenalidomide even if you have had a vasectomy
- If your partner does become pregnant whilst you are taking lenalidomide or within 7 days after you have stopped taking lenalidomide, 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 lenalidomide you should tell your prescriber or pharmacist.

Women of Non-Childbearing Potential

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

- **Lenalidomide 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 lenalidomide, your prescriber will complete a Treatment Initiation Form documenting that you are not able to become pregnant
- You should never share lenalidomide 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 lenalidomide you should tell your prescriber or pharmacist.

Lenalidomide 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 lenalidomide:

- 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 lenalidomide 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 lenalidomide. 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 lenalidomide.

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 lenalidomide 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

What to do if you have taken more than the prescribed dose of lenalidomide:

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

What to do if you forget to take your lenalidomide:

If you forget to take your lenalidomide and you remember within 12 hours of the missed dose, you can take your lenalidomide as soon as you remember and continue with the next dose at the normal time. If it is more than 12 hours since the missed dose, leave out that dose altogether and take the next dose at the normal time.

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

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

End of Treatment Requirements

After completing your lenalidomide treatment, it is important that:

- You return any unused lenalidomide 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 lenalidomide 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:

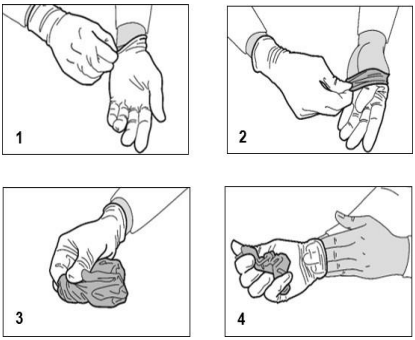
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of the powder into the air. Add excess liquid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

Tick	All Patients
	Yes, I have received and understood all the information on the risks of birth defects associated with taking lenalidomide.
	Yes, I have received and understood all the information on the risks of other side effects associated with taking lenalidomide.
	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 form before starting treatment.
	Yes, I have understood that I should never share lenalidomide 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 lenalidomide, 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 lenalidomide.

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 lenalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped lenalidomide 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 guide is produced by KRKA

Contact Details

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

Medical Information: Telephone ✆: +353 1 413 3710
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Data Protection:
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KRKA

Information for Patients and Healthcare Professionals (HCP):

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

Female patients of childbearing potential must always use effective contraception

Female patients of childbearing potential must have pregnancy tests 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 lenalidomide, patients should read the Package Leaflet and HCP should read the Summary of Product Characteristics

Date of preparation of text: 2024 IE/ver2.0 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

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.

Date of preparation of text: 2024 IE/ver2.0 HPRA Approved: 2024

Information for Healthcare Professionals (HCP):

Prescription Details

This patient is receiving lenalidomide for treatment of:

•
•
•
•

Emergency Contact Information

Emergency Prescriber Contact:

Telephone number during office hours:

Telephone number after office hours:

Further information is available in the patient guide.

Date of preparation of text: 2024 IE/ver2.0 HPRA Approved: 2024

Combined Checklist For Commencing Lenalidomide Treatment

This checklist will help you advise patients before they start treatment with Lenalidomide to ensure safe and proper use of the medicine. Please select the appropriate column for the patient risk category and refer to the counselling messages provided.

Counselling: Have you informed your patient or checked:	**Male patients**	**Women of non-childbearing potential***	**Women of childbearing potential**
on the expected risk of teratogenic effects in the unborn child?			
on the need for reliable contraception** at least 4 weeks before the start of the treatment, throughout the duration of treatment, including dose interruptions, and for at least 4 weeks after the end of treatment or about the need for complete and uninterrupted sexual abstinence?	not required	not required	
that even in case of amenorrhea, the advice on contraception** should be followed?	not required	not required	
that the patient is capable of complying with contraceptive measures?		not required	
which are the reliable contraceptive methods** female patient or female partner of a male patient can use?		not required	
on the expected consequences of pregnancy and the urgency of immediate counselling if there is a possibility of pregnancy?		not required	
on the need to discontinue treatment immediately if female patient suspects they are pregnant?	not required	not required	
that if the female partner becomes pregnant while the male patient is taking lenalidomide or soon after treatment with lenalidomide has been stopped, the prescribing doctor should be informed and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice		not required	not required
about the need to use condoms throughout the course of treatment, during dose interruptions and for at least 7 days after the end of treatment, even if the patient had vasectomy, as semen may still contain lenalidomide, even if there is no sperm present, if female partner is pregnant or of childbearing potential and does not use reliable contraception methods?**		not required	not required
that during treatment, during dose interruptions and for at least 7 days after stopping the treatment the patients should not donate semen or sperm?		not required	not required
on risks and emergency precautions related to the use of lenalidomide?			
that the medicine should not be given to others and unused capsules should be returned to the dispensing pharmacist?			
about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide			
that the patient should not donate blood while taking lenalidomide, during dose interruptions and for at least 7 days after stopping the treatment?			
your patient agrees to take pregnancy test in at least 4-weekly intervals, except in the case of confirmed tubal sterilisation?	not required	not required	
the patient had a negative pregnancy test before onset of treatment, even if she is completely and continuously sexually abstinent?	not required	not required	

*to determine whether female is of non-childbearing potential, see Information in Healthcare Professionals Guide

**for information regarding contraception see Information in Healthcare Professionals Guide

Contraceptive referral	**Male patients**	**Women of non-childbearing Potential***	**Women of childbearing potential**
Contraceptive referral required	not required	not required	
Contraceptive referral made	not required	not required	
Contraceptive consultation completed	not required	not required	

Contraception Patient is currently established on one of the following for at least 4 weeks	**Male patients**	**Women of non-childbearing Potential***	**Women of childbearing potential**
Implant	not required	not required	
Levonorgestrel-releasing intrauterine system (IUS)	not required	not required	
Medroxyprogesterone acetate depot	not required	not required	
Tubal Sterilisation (female sterilisation)	not required	not required	
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	not required	not required	
Ovulation inhibitory progesterone-only pills (i.e. desogestrel) (progestogen-only pill that prevents release of an egg from the ovaries)	not required	not required	
Patient commits to complete and absolute abstinence	not required	not required	
Negative pregnacy test before starting treatment	not required	not required	

Not of childbearing potential One of the following criteria have been met to determine if the woman is of non-childbearing potential	**Male patients**	**Women of non-childbearing Potential***	**Women of childbearing potential**
Age ≥ 50 years and naturally amenorrhoeaic***for ≥ 1 year not induced by chemotherapy	not required		not required
Premature ovarian failure confirmed by a specialist gynaecologist	not required		not required
Bilateral salpingo-oophorectomy	not required		not required
XY genotype, Turner syndrome or uterine agenesis	not required		not required

***Amenorrhoea following cancer therapy or during breast-feeding does not rule out childbearing potential

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 COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

Lenalidomide Treatment Initiation Form

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

IRELAND

This Treatment Initiation Form must be completed for each patient prior to the initiation of their lenalidomide treatment.

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

The aim of the Treatment Initiation 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 effects associated with the use of lenalidomide. 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***

Prescribers:
For female patients 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: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. 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 lenalidomide 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)	
• I understand that lenalidomide is expected to be harmful to an unborn baby and that severe birth defects may occur with the use of lenalidomide. 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 lenalidomide.	TICK
• I have read the lenalidomide patient booklet and understand the contents.	TICK
• I understand that lenalidomide 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, 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 lenalidomide.	TICK
• I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each lenalidomide 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 lenalidomide 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 Lenalidomide*.	TICK

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

PART B (only for Female Patients of Childbearing Potential)	
• I understand that I must not take lenalidomide 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 lenalidomide. I understand that I must comply with the advice on contraception even if monthly menstrual bleedings are not present during therapy.	TICK
• I understand that that even if I have amenorrhoea I must comply with advice on contraception.	TICK
• I understand that before starting lenalidomide 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 lenalidomide 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
Patient signature:	**Date:** DD MM YYYY

PART C (only for Male Patients)	
• I understand that lenalidomide 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 lenalidomide even if I have had a vasectomy.	TICK
• I understand that if I think my partner may be pregnant whilst I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide 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 lenalidomide, 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 signature:	**Date:** DD MM YYYY

Patient confirmation

I confirm that the prescriber explained the risk of teratogenicity and other adverse effects associated with the use of lenalidomide. I confirm that I understand and will comply with the requirements of the lenalidomide Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with lenalidomide.

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 lenalidomide.

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

*Your personal data is used solely for the purpose of entering you into the Lenalidomide Pregnancy Prevention Programme and is processed by the Marketing Authorisation Holder (MAH) of the lenalidomide 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 lenalidomide product you receive.
Your pharmacist can confirm the details of the MAH for the lenalidomide 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 Female Patients of Childbearing Potential (Part D) and Males (Part E)

PART D (Confirm for Female Patients of Childbearing Potential)

Contraceptive referral for Female Patients 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 Female Patients of Childbearing Potential

The patient has been established on one of the following

• 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

Lenalidomide treatment cannot start until the patient has been established on at least one effective method of contraception for 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

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

PART E (Confirm for Male Patients)

Pregnancy Prevention for Male Patients

The patient confirms that:

• They will use a condom during intercourse with a female 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

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

Prescribers Confirmation

I confirm that:

- I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with lenalidomide, 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 lenalidomide Pregnancy Prevention Programme.
- I will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

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

Lenalidomide Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY lenalidomide 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:						
Indication (tick)						
☐ Multiple Myeloma						
☐ Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality						
☐ Mantle Cell Lymphoma relapsed and/or refactory						
☐ Follicular Lymphoma						
☐ Other (please specify) _____						
Capsule strength prescribed (tick) / Quantity of capsules prescribed(*do not enter number of packs)						
☐ 2.5 mg	☐ 5 mg	☐ 7.5 mg	☐ 10 mg	☐ 15 mg	☐ 20 mg	☐ 25 mg
Quantity*	Quantity*	Quantity*	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 lenalidomide 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 lenalidomide.

Prescriber's declaration

As the Prescriber, I have read and understood the lenalidomide 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 lenalidomide. 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

Pharmacist's declaration

I am satisfied that this **Lenalidomide** Prescription Authorisation Form has been completed fully and that I have read and understood the **Lenalidomide** 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	
Lenalidomide Brand dispensed	

Lenalidomide 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 lenalidomide for your patient. This will enable the community pharmacy to register with the Lenalidomide Pregnancy Prevention Programme and subsequently be able to order and dispense lenalidomide for your patient.

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

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 lenalidomide for their patient. The patient has nominated your pharmacy to dispense the prescription.

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

If you choose to dispense Lenalidomide Krka, you must register with KRKA, using the Lenalidomide Krka (lenalidomide) 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 lenalidomide please contact KRKA on +353 1 413 3710.

Lenalidomide Krka (lenalidomide) Pharmacy Registration Form

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

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

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

1	I have read and understood the Lenalidomide Krka Healthcare Professional's Information Guide.	TICK
2	All pharmacists who dispense Lenalidomide Krka will have read and understood the Lenalidomide Krka Healthcare Professional's Information Guide.	TICK
3	If supplied with Lenalidomide 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 Lenalidomide Krka will be dispensed only if accompanied by a completed Lenalidomide Prescription Authorisation Form.	TICK
5	The pharmacist dispensing Lenalidomide 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	Lenalidomide 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 Lenalidomide Krka to women of childbearing potential should occur within 7 days of the prescription.	TICK
10	After dispensing, Lenalidomide 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 Lenalidomide Krka will only be granted if I agree to items 1–12 described above as supply of Lenalidomide 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

Lenalidomide Krka (lenalidomide) 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) 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 lenalidomide being prescribed	Date of prescription DD MM YYYY

Product Description	**Strength**	**Quantity required**
Lenalidomide capsules	5 mg	
Lenalidomide capsules	10 mg	
Lenalidomide capsules	15 mg	
Lenalidomide capsules	25 mg	

Comments:

I confirm that I am ordering on behalf of a registered pharmacy and that Lenalidomide Krka will be dispensed in accordance with the risk minimisation procedures for lenalidomide, as specified by KRKA in the Lenalidomide 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

Lenalidomide Krka (lenalidomide) 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:	Pharmacy GMS code:

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 lenalidomide being prescribed	Date of prescription DD MM YYYY

Product Description	**Strength**	**Quantity required**
Lenalidomide capsules	5 mg	
Lenalidomide capsules	10 mg	
Lenalidomide capsules	15 mg	
Lenalidomide capsules	25 mg	

Comments:

I confirm that I am ordering on behalf of a registered pharmacy and that Lenalidomide Krka will be dispensed in accordance with the risk minimisation procedures for lenalidomide, as specified by KRKA in the Lenalidomide 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:

Lenalidomide Krka (lenalidomide) 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 lenalidomide.
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 lenalidomide.

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 lenalidomide):	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:			

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.

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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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.

Lenalidomide Krka (lenalidomide)

Adverse Event (AE) Form

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

For KRKA use only					**Case no:**
Date of receipt: DD MM YYYY					
Received by:					
Report type:		☐ New			☐ Follow up
Source:	☐ literature	☐ Health professional	☐ Patient	☐ Other (sepecify)	
For studies enter:		Protocol no:	Site no:	Patient no:	

Patient Data					
Initials:	Date of birth: DD MM YYYY	Age:	Weight (kg):	Heigth(cm):	Sex:

Suspected Drug						
Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)	**Dose & frequency**	**Lot/ Batch no.**	**Therapy start date**	**Therapy end date**	**Drug-Event Causal relationship (1 = Not related, 2 = Related); Other, Specify**	**Indication for use of drug**
			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		

Action taken						
☐ None	☐ Unknown	☐ Not applicable	☐ Dose decreased, specify	☐ Dose increased, specify	☐ Permanently discontinued	☐ Temporarily interrupted

Adverse Event	Event on-set date: DD/MM/YYYY	Event stop date: DD/MM/YYYY	Or ongoing at time of reporting (If less than 24 hours):HOUR/MIN

Description of Adverse Event (provide diagnosis if available) -symptoms and treatment:

Outcome of Adverse Event	☐ Recovered	☐ Recovered with sequelae	☐ Not recovered	☐ Unknown
	☐ Death	Date of death:DD/MM/YYYY	Cause(s) of death:	
	Did the event result in hospitalisation or prolonged hospitalisation? YES/NO:		**If autopsy is performed please forward report. Please attach relevant clinical laboratory assessments to confirm the event**	

Medical History

☐ Yes, please specify
☐ None
☐ Unknown

Other Medication (Medication taken in the last 3 months prior to the event)

Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)	**Dose & frequency**	**Therapy start date:**	**Therapy end date:**	**Indication for use of drug**
		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	

Has the patient discussed this event with their healthcare professional?	☐ No
	☐ If yes, would you please provide their healthcare professional's contact information below?
	☐ Unknown

Healthcare professional's contact information	
Name:	Phone:
Address:	Email:
	Fax:
Pharmacy Name (if applicable):	
Name:	**Email:**

Reporter details	
Profession:	Phone:
Name:	Email:
Address:	Fax:
Signature:	Date of AE awareness: DD/MM//YYYY

Data Privacy Notice

We would like to notify you that you will share your personal data (aggregated anonymised patient limited data e.g., patient intials, date of birth) with KRKA SUBSIDIARY when you'll report adverse reaction or ask a question about the safety of our medicine. Because of the new EU data protection legislation, we have to inform you that:

- We will process your data only for these purposes.

- That we have an obligation to process them and to store them permanently according to legislation governing medicinal products.

- Personal data protection policy and the rights of individuals are available on our website (www.krka/biz).

Frequently Asked Questions (FAQs)

What must I do prior to prescribing lenalidomide?

Prescribers wishing to prescribe lenalidomide must read the lenalidomide 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 lenalidomide.

What are the maximum prescription lengths for treatment with lenalidomide?

The maximum prescription lengths for treatment with lenalidomide 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 lenalidomide?

Pharmacies choosing to purchase or dispense Lenalidomide Krka must register with KRKA using the Lenalidomide Krka (lenalidomide) 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 lenalidomide.

Do I need a registration number to order lenalidomide?

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 Lenalidomide Krka.

Where do I order Lenalidomide Krka?

Once registered with KRKA, to order Lenalidomide 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 Lenalidomide Krka (lenalidomide) 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 Lenalidomide Krka Healthcare Professional's Information Guide or the patient materials?

If you would like further copies of the Lenalidomide 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 should be reported to KRKA Pharmacovigilance. Adverse Event Reporting Forms, Pregnancy Reporting Forms and Pregnancy Outcome Forms should be forwarded to KRKA 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 lenalidomide.

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 Lenalidomide 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:
To report any Adverse Events or Suspected Pregnancies, or to obtain Medical Information on Lenalidomide KRKA products
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 Lenalidomide 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, Lenalidomide Krka Pregnancy Prevention Programme, Pharmacy Registrations, and the use of the Prescription Authorisation Form and to order hard copies of any of the Lenalidomide 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 Lenalidomide 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

KRKA Pharma Dublin Limited
Office H, 1st Floor
Citywest Shopping Centre
Citywest Drive, Citywest
Dublin 24, Co. Dublin
D24 TYT9
Ireland

IE/ver2.0; Date of texts preparation: February 2024; HPRA Approved: February 2024