Lenalidomide Rowex

Healthcare Professional's Information Pack

Ireland

Important Safety Information

Healthcare Professionals involved in the prescribing or dispensing of lenalidomide must read and understand the information contained in this guide.

For complete safety information please refer to the Summary of Product Characteristics (SmPC) for Lenalidomide Rowex available at the following website: HPRA www.hpra.ie

Version 2

Feb 2024

Information for Healthcare Professionals

This section contains information for healthcare professionals prescribing or dispensing lenalidomide.

Contents

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Lenalidomide Pregnancy Prevention Programme and Information for Healthcare Professionals involved in the prescribing or dispensing of lenalidomide.

This guide contains the information 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 Rowex 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 (HCPs) ensure that they have read and understood this 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 refer to the Lenalidomide Rowex Summary of Product Characteristics (SmPC). This can be found on the following website: www.hpra.ie

Contents

1. Introduction

1.1. Licenced indication and posology

Lenalidomide is an immunomodulating medicinal product.

Lenalidomide Rowex 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 Rowex 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 Rowex 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 Rowex 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 to initiation of treatment.

1.2 Posology

Newly Diagnosed Multiple Myeloma
Lenalidomide Maintenance in Patients who have Undergone Autologous Stem Cell Transplantation (ASCT) 2022
The recommended starting dose of lenalidomide is 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/m2 body surface area subcutaneously twice weekly on Days 1, 4, 8 and 11 of each 21-day cycle. 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 orally once daily on Days 1 to 21 of repeated 28-day cycles for up to 9 cycles, melphalan 0.18 mg/kg orally on Days 1 to 4 of repeated 28-day cycles, prednisone 2 mg/kg orally on Days 1 to 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 monotherapy as follows:
10 mg orally once daily on Days 1 to 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 to 21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg orally once daily on Days 1 to 4, 9 to 12, and 17 to 20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg once daily on Days 1 to 4 every 28 days. The prescriber 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.

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/m2 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 – 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 4mg/kg/day. Findings from this study showed that lenalidomide produced external malformations (short limbs, bent digits, wrist and/or tail, supernumerary or absent digits) 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 is expected.
Therefore, lenalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met.

2. Lenalidomide Rowex Pregnancy Prevention Programme

• It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood this guide before prescribing or dispensing lenalidomide 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 (this must be documented via a Treatment Initiation Form and checklists for counselling which are available for this purpose).

• The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in the Algorithm contained within this guide.

• Patients should be capable of complying with the requirements of safe use of lenalidomide.

• Patients must be provided with the appropriate Patient Guide, Treatment Initiation Form and Patient Pocket Information Card.

All of the lenalidomide Rowex Pregnancy Prevention Programme materials are available electronically on the HPRA website: www.HPRA.ie (enter 'Lenalidomide Rowex' under 'Find a Medicine' and click 'EdM' under the 'Documents' column). Additional hard copies can be obtained from Rowex 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 Rowex will only be allowed from pharmacies registered with Rowex Ltd.
Rowex Ltd. will not authorise supply of Lenalidomide Rowex to pharmacies that are not registered with Rowex.

2.1 The following are core requirements of the Pregnancy Prevention Programme:

- A controlled distributing system
- All HCPs dispensing or prescribing lenalidomide must read and understand the lenalidomide HCP's Information Guide
- All prescriptions for lenalidomide must be accompanied by a lenalidomide Prescription Authorisation Form, which must be completed by the prescriber and the pharmacist
- All pharmacies who dispense Lenalidomide Rowex must implement risk minimisation by registering with the Rowex Pregnancy Prevention Programme and in accordance with the measures described in this guide.

2.2 Safety advice to avoid foetal exposure

- **2.2.1 Women of non-childbearing potential**

Women in the following group 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. Please note amenorrhea following cancer therapy or during lactation does not rule out childbearing potential
- Premature ovarian failure 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 at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

➢ 2.2.2 Women of child-bearing potential

Women of childbearing potential must never take lenalidomide if they are:

- Pregnant
- Able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

In view of the expected teratogenic risk of lenalidomide, foetal exposure must be avoided. Women of childbearing potential (even if they have amenorrhea) must:

- Use one effective method of contraception (see below) for 4 weeks before therapy, during therapy, and until 4 weeks after lenalidomide therapy, and even in case of dose interruption

or

- Commit to absolute and continuous sexual abstinence

and

- Have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/ml) once established on contraception for 4 weeks, at 4-weekly intervals during therapy and 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This also includes those women of childbearing potential who confirm absolute and continued sexual abstinence.

There must be no more than **3 days** between the dates of the last 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 HCP 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 sterilization
- 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 Rowex, she must immediately stop treatment and inform her physician.

Refer the woman to a physician specialised or experienced in teratology for evaluation and advice.

Notify Rowex Ltd. immediately of all such occurrences by contacting Rowex Ltd. Drug Safety Department (Tel: 02750077) or email: pv@rowa-pharma.ie Please also complete the Pregnancy Reporting Form. Rowex Ltd. will wish to follow-up with you the progress of all pregnancies.

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

- **2.2.3 Men**

In view of the expected teratogenic risk of lenalidomide, foetal exposure should be avoided.

Pharmacokinetic data has demonstrated that lenalidomide is present in human semen at extremely low levels during treatment and is undetectable in human semen 3 days after stopping the drug in the healthy subject.

As a precaution, all male patients taking lenalidomide should be informed of the following:

- The effective contraceptive methods that his female partner can use.
- If their partner is pregnant or of childbearing potential and not using effective contraception, that the male patients should use condoms throughout the duration of treatment, during dose interruption and for 1 week after cessation of treatment, even if the male patient has undergone a vasectomy.
- If pregnancy occurs in a partner of a male patient whilst he is taking lenalidomide or within 7 days after he has stopped taking lenalidomide, he should inform his prescriber immediately. The partner should inform her prescriber immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice.
- Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of lenalidomide.

If the partner of a male taking Lenalidomide Rowex becomes pregnant, he must inform his physician immediately. Then refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.

Notify Rowex Ltd. immediately of all such occurrences by contacting Rowex Ltd. Drug Safety Department (Tel: 02750077) Please also complete the Pregnancy Reporting Form. Rowex Ltd. will wish to follow-up with you the progress of all pregnancies.

Suspected pregnancies can also be reported via the HPRA Pharmacovigilance website: **www.hpra.ie**

Points to Consider for Handling the Medicinal Product: For Patients, Healthcare Professionals and Caregivers

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.

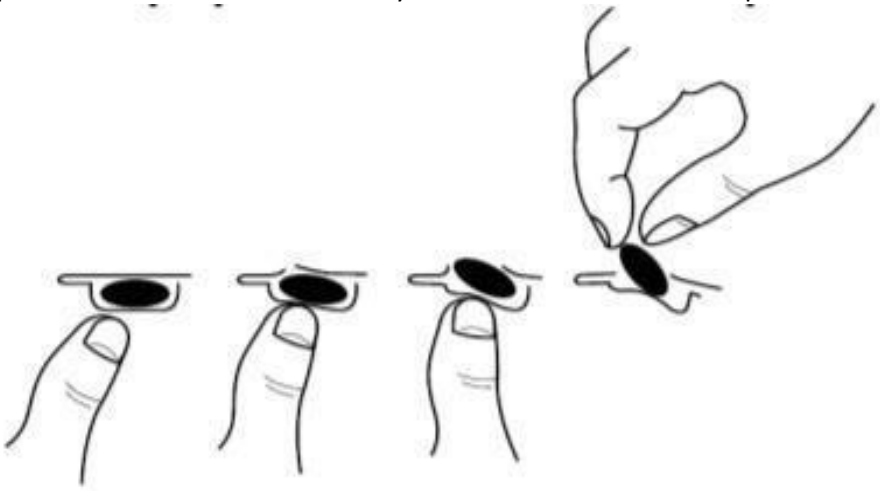
Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

Healthcare professionals and caregivers 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.

It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.



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 package appears visibly damaged, use the following extra precautions to prevent exposure:

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

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

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products
- Wash your hands thoroughly with soap and water after removing the gloves
- Please report to Rowex Ltd.

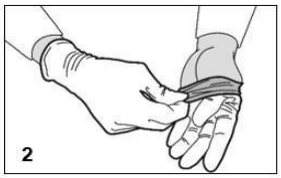
If the contents of the capsule are attached to the skin or mucous membranes

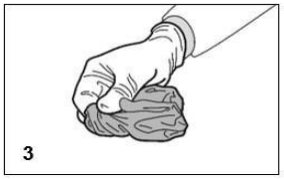
- If you touch the drug powder, please wash exposed area thoroughly with running water and soap
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation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

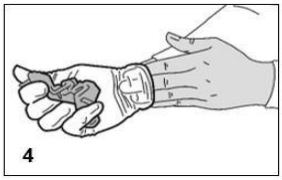
Proper Technique for Removing Gloves:

- 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.







2.3 Prescribing and Dispensing lenalidomide

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

➢ 2.3.1 Maximum prescription lengths

You may prescribe a maximum of four weeks of therapy for women of childbearing potential, or twelve weeks of therapy for all other patients and continuation of treatment requires a new prescription.

➢ 2.3.2 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 their 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.

➢ 2.3.3 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.

– Perform a pregnancy test, if relevant.

• Provide a 'Prescription Authorisation Form' to the patient or submit electronically to the pharmacy with each lenalidomide prescription.

All prescribers must have read and understood the information contained within the Healthcare Professional Information Guide before prescribing lenalidomide Rowex.

➢ 2.3.4 Prescription Authorisation Form

A completed Prescription Authorisation Form must accompany every prescription.

The patient must present their 'Prescription Authorization Form' to the pharmacy for each 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 Prescriber must confirm 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.
- 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.
- 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.
- 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 PAF 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 chemotherapy.

The Pharmacist must confirm on the Prescription Authorisation Form:

- That the Prescription Authorization Form has been completed in full by the prescriber
- That dispensing 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 this guide.

If any information is missing the pharmacist should contact the prescriber for verification prior to dispensing.

The Prescription Authorisation From should be retained with the High-Tech Prescription in the pharmacy.

2.4 Dispensing Lenalidomide

It is a requirement of the Pregnancy Prevention Programme that pharmacies wishing to purchase and dispense Lenalidomide Rowex are registered with Rowex Ltd. Registration involves reading and understanding the Healthcare Professional's Information Guide, completing and signing the Pharmacy Registration Form and e-mailing or posting the completed form to Rowex Ltd. to indicate agreement and compliance with the content.
In order to be registered, the Chief Pharmacist/Superintendent 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 Rowex will only be allowed from pharmacies registered with Rowex Ltd.
Rowex Ltd. will not authorise purchase and supply of Lenalidomide Rowex to pharmacies not registered with Rowex Ltd.

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

2.4.1 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 Rowex, it must first contact Rowex to register with them using the **Lenalidomide Rowex Pharmacy Registration Form**. Rowex will then send the pharmacy the relevant documentation if not already received.

2.4.2 Ordering lenalidomide

The pharmacy must be registered with Rowex Ltd. to order lenalidomide Rowex. To order Lenalidomide Rowex the pharmacy must use a specific lenalidomide Rowex order form (available on request from Rowex 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.

2.4.3 Dispensing Advice

2.4.3.1 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.

2.4.3.2 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.

2.4.2.3 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 to the pharmacy. Pharmacies must accept any unused lenalidomide returned by patients for destruction and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.
  Please ensure that all pharmacists within your pharmacy are educated about and familiar with the requirements of the PPP and the dispensing procedures for lenalidomide.

3. Follow-up

3.1 Follow-up assessment of the effectiveness of the Programme and monitoring of off-label use

The terms of the Lenalidomide Rowex Marketing Authorization require Rowex Ltd. to assess the effectiveness of the Pregnancy Prevention Programme in order to ensure that all reasonable steps are being taken to reduce the risk of pregnancy in patients treated with lenalidomide as well as to monitor for off- label use.
Pharmacies can therefore fulfill their obligations in this respect, by conducting a n annual self- audit of the prescription authorization forms, against which the pharmacy has dispensed lenalidomide Rowex and reporting appropriately anonymised and aggregated results to Rowex Ltd. This information will be provided in an anonymous and aggregated format to the HPRA. Rowex Ltd. will supply pharmacists with a self-audit pack, such that self-auditing of pharmacies and feedback of the audit results to Rowex Ltd. can occur.
It is critical, therefore, that all documentation associated with the Pregnancy Prevention programme are completed accurately, and that the audit results are provided faithfully and diligently, in the interest of patient safety.

4. Other selected Risks of Lenalidomide

The following section contains advice to HCPs about how to minimise the risk of the principal adverse events associated with the use of lenalidomide. For a full list of the adverse events that may be associated with its use please refer to the Lenalidomide Rowex SmPC.

4.1 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 with 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 practised 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 prescriber's discretion, lenalidomide may be continued in patients with Grade 1 or 2 TFR, without interruption or modification. At the prescriber'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.

4.2 Second primary malignancies

An increase of second primary malignancies (SPM) has been observed in clinical trials in previously treated myeloma patients receiving lenalidomide/dexamethasone (3.98 per 100 patient-years) compared to controls (1.38 per 100 patient-years). 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.
The risk of occurrence of SPM must be taken into account before initiating treatment with lenalidomide either in combination with melphalan or immediately following high dose melphalan and ASCT. Physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

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).

4.3 Disposal of unwanted medicine

Patients must be advised never to give lenalidomide to another person and to return any unused capsules to their pharmacist at the end of the treatment.

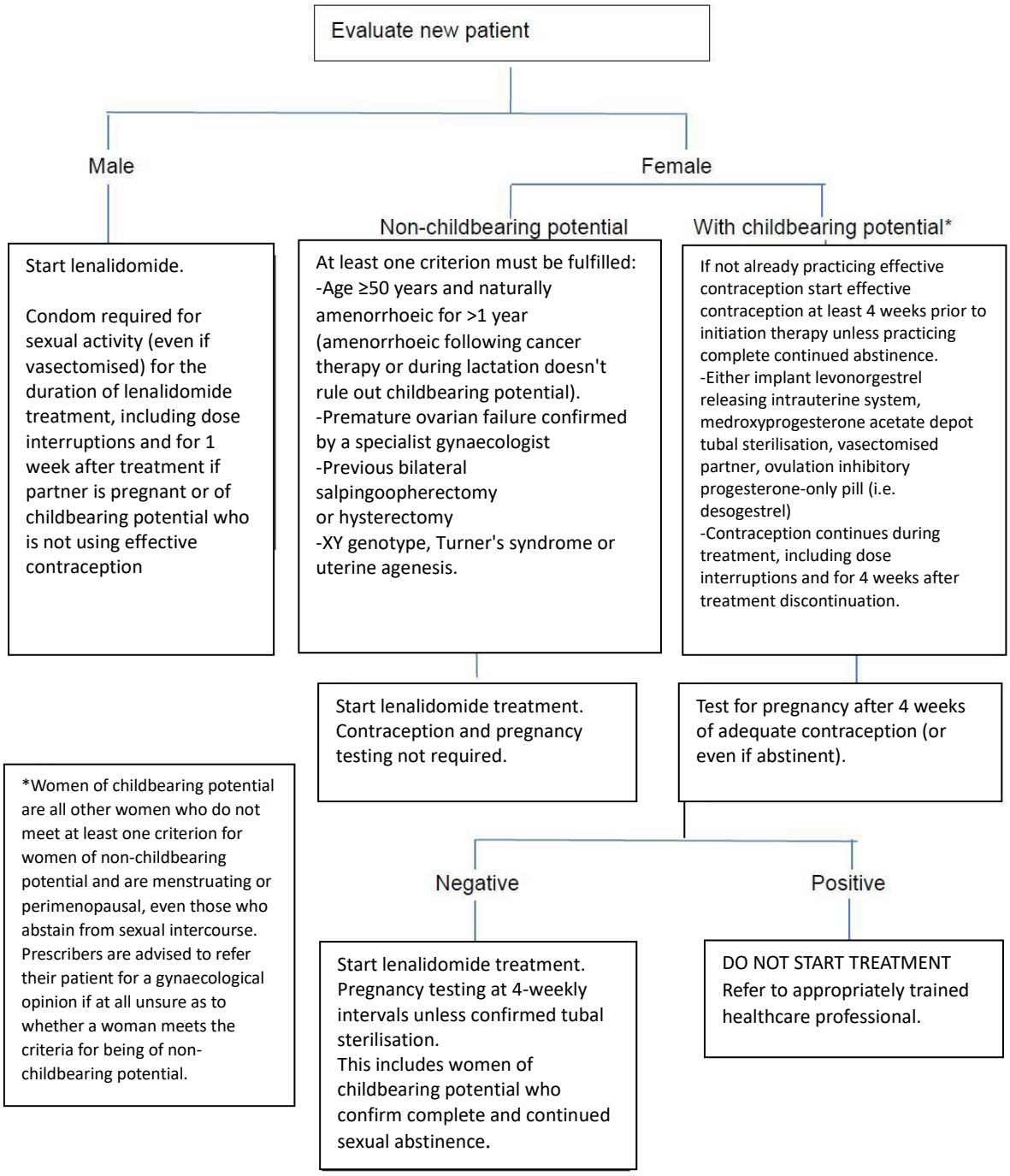
4.4 Blood donation

Patients should not donate blood during treatment, including during dose interruptions and for at least 1 week after cessation of treatment with lenalidomide.

5. Reporting of Adverse Reactions

The safe use of lenalidomide is of paramount importance.
Adverse events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Adverse event report forms and pregnancy reporting forms should be forwarded to the Rowex Ltd. Drug Safety Department (See contact details) or to HPRA Pharmacovigilance www.hpra.ie

Lenalidomide
Description of the Pregnancy Prevention Programme (PPP) and Patient Categorisation.



Prescribers Guide to Prescribing lenalidomide

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 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 must read the Healthcare Professional's Information Guide.
2. Please complete a 'Community Pharmacy Dispensing Notification Form' to notify the nominated community pharmacy that their patient will be presenting with a prescription for lenalidomide. Fax 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'.

Pharmacist Guide to Dispensing lenalidomide

In order to dispense Lenalidomide Rowex:

As a nominated community pharmacy, you will receive a 'Community Pharmacy Dispensing Notification Form' from the prescriber / 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 Rowex Ltd.

1. Contact Rowex Risk Management on 1800 304 400 to obtain a Healthcare Professional's Information Guide which includes all relevant information, pharmacy registration forms and order forms.
2. Read the Guide.
3. Complete 'Pharmacy Registration Form' and fax to Rowex on 027 50417. Or email pv@rowa-pharma.ie You will be notified when you have been registered.
4. Once you are informed that you are registered with Rowex, complete a 'Lenalidomide Rowex Order Form'.
5. Fax or email UDD 'UDD Lenalidomide Rowex Order Form' to UDD on 01 463 2404 or **specialorders@united-drug.com**
   UDD aim to deliver complete orders placed before 13:30 Monday to Friday for the following working day.
6. For orders through Uniphar fax or email ' Uniphar Lenalidomide Rowex Order Form' to Rowex on 02750417 or email **specialorders@rowa-pharma.ie**

You are a Community Pharmacy that has previously registered with Rowex

1. Complete a 'Lenalidomide Rowex Order Form'.
2. For orders through UDD:
   Fax or email 'UDD Lenalidomide Rowex Order Form' to UDD on 01 463 2404 or specialorders@united-drug.com.
   UDD aim to deliver complete orders placed before 13:30 Monday - Friday for the following working day.

Or

3. For orders through Uniphar:
   Fax or email 'Uniphar Lenalidomide Order Form' to Rowex on 02750417 or specialorders@rowa-pharma.ie

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

Complete 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 Prescription Authorisation Form. The form is used within the Pregnancy Prevention Programme and must be completed each time you prescribe lenalidomide.

Prescription Authorisation Form

1	Name of treating hospital			Both signatures must be present prior to dispensing lenalidomide
2	Patient date of birth DD MM YYYY	Patient ID number/Initials:		**Prescriber's declaration** As the Prescriber, I have read and understood the 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.
3	Prescriber: (print) Supervising physician name (print)		8	Sign / Print Date / Bleep
4	Indication (tick)	Multiple myeloma □ Mantle cell lymphoma relapsed and/or refractory □ Myelodysplastic syndromes with isolated del5qcytogenetic abnormality □ Follicular lymphoma □ Other (please specify) □	A	**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, the dispensing will be taking place within 7 days of the date of prescription. I am dispensing no more than a 4 week supply to women of childbearing potential and 12 weeks for males and women of non- childbearing potential
5	Capsule strength prescribed: (tick) 2.5mg□ 5mg□ 7.5mg□ 10mg□ 15mg□ 20mg□ 25mg□		B	Sign / Print Date / Bleep
	Quantity of **Capsules** prescribed: * * Do **NOT** enter number of packs			Name and postcode of dispensing pharmacy
	Enter the cycle number(s) prescribed for this patient			
	Please tick all boxes that apply			
	Woman of non-childbearing potential Yes □ No □			
	Male Yes □ No □			
6	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). Yes □ No □		E	Lenalidomide brand dispensed
Note to pharmacist – Do not dispense unless ticked YES for Male patients □				
	Woman of childbearing potential Yes □ No □ 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. Yes □ No □			
7	Date of last negative pregnancy test:			
Note to pharmacist – Do not dispense unless ticked yes and a negative test has been conducted within 3 days prior to the prescription date and dispensing is taking place within 7 days of the prescription date				

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.

Instructions for pharmacists

A. Check that all relevant sections of the form have been fully completed by the prescriber, including:
a. That counselling and contraceptive measures have been confirmed by the prescriber as appropriate.
b. That for woman of childbearing potential a negative pregnancy test date is provided within 3 days of the prescription date.
c. The indication, capsule strength, capsule quantity and number of cycles have been provided.
B. Check the form does not contain confidential information

5. Print the diagnosis/indications – this is for purpose of monitoring off label use.
6. Enter the capsule strength, quantity of capsules prescribed and the number of cycles prescribed.
7. Complete this section appropriately to indicate that counselling has occurred and appropriate contraception measures ae 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 3days prior to prescribing). If this is not the case 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.

(e.g., Patient Name and Hospital Number).
C. Check the form is complete and legible.
D. You must sign, date and print your name to declare that the form has been completed fully and dispensing is taking place within 7 days of the date of prescription for women of childbearing potential.
i. Dispense only a maximum of 4 weeks supply for women of childbearing potential at any one time.
ii. Dispense only a maximum of 12 weeks supply for Males and Women of Non-childbearing Potential.
E. Record the brand of lenalidomide dispensed for each dispensing cycle the PAF was used for. This will assist in completion of the pharmacy self-audit for the particular lenalidomide brand.

Further information and materials are available from:
Rowex Ltd.
Tel 027 50077
Email: pv@rowa-pharma.ie

Mandatory Lenalidomide Rowex Order Forms

Following discussions with the Health Products Regulatory Authority (HPRA) compliance with the PPP will also be monitored through Lenalidomide Rowex 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 Distributor (UDD) to Rowex who will then compile anonymised and aggregated data reports to provide to the HPRA on an annual basis.

Rowex will keep the order forms for orders through Uniphar and will provide Uniphar with a copy.

Prescribing and dispensing of lenalidomide

Pharmacist

Prescriber

Identify patients for lenalidomide, obtain **Healthcare Professional's Information Guide** from Rowex

Read Guide, fax Pharmacy Registration Form to Rowex

Read and understand the Guide

Patient presents at pharmacy, pharmacist:

- Cross-checks Prescription Authorisation Form
- Signs Prescription Authorisation Form
- Orders lenalidomide Rowex via the Lenalidomide Rowex order form
- Dispenses lenalidomide Rowex to patient
- Retains Prescription Authorisation Form for a minimum of two years.
- Sends self-audit/ reconciliation to Rowex as arranged.

Pharmacies must undertake the mandatory annual self-audit of the Prescription Authorisation Forms and provide feedback of the audit results to Rowex.

Identify patient for lenalidomide:

- Inform patient about pregnancy prevention
- Complete 'Treatment Initiation form'
- Complete 'Prescription authorisation form'
- Provide patient educational materials
- For first prescription, notify the pharmacy of an incoming prescription via the 'Community pharmacy Dispensing Notification form'.

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

6. Contact Details

Risk Management:
For information and questions on the risk management of the Rowex Ltd. products, the Pregnancy Prevention Programme, pharmacy registrations and the use and submission of the Prescription Authorisation Form:
Tel: 027 50077 Email: pv@rowa-pharma.ie

Drug Safety:
To report any adverse events to Rowex Ltd.
Tel: 027 50077 Email: pv@rowa-pharma.ie
You can also report side effect directly via the HPRA Pharmacovigilance website:
www.hpra.ie

Medical Information:
To obtain Medical Information
Tel: 027 50077 Email: pv@rowa-pharma.ie

Data Protection:
Any queries regarding Data Protection
Tel: 027 50077 Email: rowex@rowa-pharma.ie

Distributor:
United Drug Distribution (UDD) Tel: 01 463 2478
United Drug House Fax: 01 463 2404
Magna Business Park Email: specialorders@united-drug.com
Citywest Road
Dublin 2

Or

Uniphar Group Reception 01 428 7777
4045 Kingswood Road Customer Service 01 4687501
Citywest Business Park Email: info@uniphar.ie
Co. Dublin Orders: specialorders@rowa-pharma.ie
D24 VO6K Orders fax: Tel 027 50417

Lenalidomide Pregnancy Prevention Programme Patient Guide

Information for Patients taking Lenalidomide.

IRELAND

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 LENALDIOMIDE 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 disposal of unused lenalidomide capsules.

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 doctor 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

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 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.
  - You are a woman who is 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 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. You will be asked to confirm this every month.

- Inform the prescriber of your contraception that you are on lenalidomide.
- Inform your prescriber of lenalidomide if you have changed or stopped the method of contraception.
- 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 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 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 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:

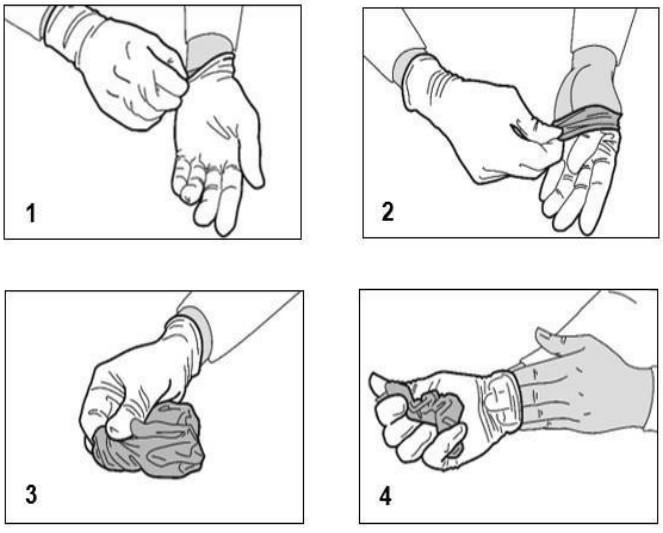
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of the powder into the air. Add excess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

Please use this checklist to confirm that you have understood all of the important information regarding your lenalidomide treatment.

All Patients

- ☐ 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.
- ☐ 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 the form before starting treatment.

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.

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).

Special monitoring

Because lenalidomide can cause a drop in white blood cell and platelet counts, you will have regular blood tests during treatment. Your prescriber will also monitor how well your kidneys are working. You will have blood tests more frequently in the first few months when you start treatment.

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. If treatment has to be stopped for any reason, your prescriber will discuss other treatment options with you.

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

This guide is produced by:
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pv@rowa-pharma.ie

Information for patients and healthcare professionals:

Patient card

Emergency contact information

Emergency prescriber contact:

Office hours: _____

Out of office hours:_____

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

Information for Patients and Healthcare Professionals:

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 vasectomy).

-If a patient or partner of a patient suspects they are pregnant they must contact their prescriber immediately.

-You MUST tell your prescriber immediately if you experience any symptoms that causes concern.

Lenalidomide Information for Healthcare Professionals

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), in the case of a WCBP, is having a pregnancy test every 4 weeks before each prescription to ensure they are not pregnant.

Information for Healthcare Professionals:

Prescription details

This patient is receiving lenalidomide for the treatment of:

Treatment Checklists

Combined checklist for commencing lenalidomide Treatment

	Women CBP	Women NCBP*	Male
Counselling			
Inform of expected teratogenic risk to the unborn child	✓	✓	✓
Inform of the need for effective contraception** 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for 4 weeks after the end of treatment or absolute and continued abstinence	✓		
Inform that even if patient has amenorrhea, they must comply with advice on contraception	✓		
Confirm patient is capable of complying with contraceptive measures	✓		✓
Inform of the expected consequences of pregnancy and the need to stop treatment and consult rapidly if there is a risk of pregnancy	✓		✓
Inform of the need to stop treatment immediately if female patient is suspected to be pregnant	✓		
Confirm patient agrees to undergo pregnancy testing at 4 weekly intervals, unless confirmed tubal sterilisation	✓		
Inform of hazards and necessary precautions associated with use of lenalidomide	✓	✓	✓
Inform patient not to share medication	✓	✓	✓
Inform to return unused capsules to pharmacist	✓	✓	✓
Inform not to donate blood whilst taking lenalidomide or for 1 week after stopping or during treatment interruptions	✓	✓	✓
Inform of need to use condoms (even if he has had vasectomy) throughout treatment duration, during dose interruption, and for one week after cessation of treatment if partner is pregnant or is of childbearing potential and not using effective contraception.			✓
Inform of the need not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following discontinuation.			✓
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	✓	✓	✓
Inform about which are effective contraceptive methods that the female patient or the female partner of a male patient can use	✓		✓
Inform that if his female partner becomes pregnant whilst he is taking lenalidomide or shortly after he has stopped taking lenalidomide, he should inform his treating physician immediately and that it is recommended to refer the female partner to a physician specialized or experienced in teratology for evaluation and advice			✓

*Refer to Healthcare Professional Information Guide for criteria to determine if patient is a woman of non-childbearing potential.

** Refer to Healthcare Professional Information Guide for information on contraception.

	Women CBP	Women NCBP	Male
Contraceptive referral			
Contraceptive referral required	✓		
Contraceptive referral made	✓		
Contraceptive consultation completed	✓		
	Women CBP	Women NCBP	Male
Contraception Patient is currently established on one of the following for at least 4 weeks			
Implant	✓		
Levonorgestrel-releasing intrauterine system (IUS)	✓		
Medroxyprogesterone acetate depot	✓		
Sterilization	✓		
Sexual intercourse with a vasectomized male partner only: vasectomy must be confirmed by negative semen analysis	✓		
Ovulation inhibitory progesterone-only pill (desogestrel)	✓		
Patient commits to complete and absolute abstinence	✓		
Negative pregnancy test before starting treatment	✓		

	Women CBP	Women NCBP	Male
Not of childbearing potential One of the following criteria have been met to determine patient is woman NCBP			
Age ≥ 50 years and naturally amenorrhoeic*** for ≥ 1 year not induced by chemotherapy		✓	
Premature ovarian failure confirmed by specialist gynaecologist		✓	
Bilateral salpingo-oophorectomy		✓	
XY genotype, Turner's syndrome, uterine agenesis		✓	

***Amenorrhea following cancer therapy or during lactation does not rule out childbearing potential CBP: childbearing potential
NCBP: non 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 PRIOR TO INITIATION OF THERAPY OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

Lenalidomide Pregnancy Prevention Programme (PPP)

Male Treatment Initiation Form

Treatment initiation form for counselling the patient to ensure the patient is fully informed about the safe use of lenalidomide.

This treatment initiation form is to assist you with counselling a patient before they commence lenalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each male prior to the initiation of their lenalidomide treatment.

The purpose of the treatment initiation from is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse drug reactions associated with the use of lenalidomide. It is mandatory that male patients receive counselling and education to be made aware of the risks of lenalidomide.

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of foetal exposure.

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 Name:																						
Patient Last Name:																						

Date of Birth:	*DD*	*MM*	*YYYY*	Counselling Date:	*DD*	*MM*	*YYYY*

Pregnancy Prevention

The patient confirms that:	
They will use a condom during intercourse with a woman of childbearing potential	*tick*
Their female partner is using an effective method of contraception	*tick*
Their female partner is of non-childbearing potential	*tick*
They are committed to complete and absolute abstinence	*tick*

Prescriber Confirmation

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 will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

Prescriber First Name:																					
Prescriber Last Name:																					
Prescriber Signature:															Date	DD	MM	YYYY			

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that severe birth defects are expected to 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.	Patient initials
I understand that lenalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't 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	Patient initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE	Patient initials
I have read the lenalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I understand that I cannot donate blood while taking lenalidomide (including dose interruptions) or for at least 7 days after stopping treatment	Patient initials
I know that I cannot donate semen or sperm while taking lenalidomide, during dose interruptions and for at least 7 days after discontinuation of lenalidomide treatment.	Patient initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about which are effective contraceptive methods that my female partner can use.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis During treatment with lenalidomide.	Patient initials
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.	Patient initials
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 Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	Patient initials

Patient Confirmation

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

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.

Should you have any queries in relation to the use of your personal data please contact the Marketing Authorisation Holder.

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.

Signed		Name (print)		Date	dd	mm	yyyy

Lenalidomide Pregnancy Prevention Programme (PPP)

Woman of Childbearing Potential Treatment Initiation Form

Treatment Initiation Form for counselling the patient to ensure the patient is fully informed about the safe use of lenalidomide.

This Treatment Initiation Form is to assist you with counselling a patient before they commence lenalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female patient of childbearing potential prior to the initiation of their lenalidomide treatment. The purpose 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 drug reactions associated with the use of lenalidomide. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of lenalidomide as it is contraindicated in women of childbearing potential unless all terms of counselling are met.

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of foetal exposure.

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 name																						
Patient Last name																						

Date of Birth	DD	MM	YYYY		Counselling Date	DD	MM	YYYY

Contraceptive Referral

Contraceptive referral required			YES	NO
Contraceptive referral made	DD	MM	YYYY	
Contraceptive consultation conducted on	DD	MM	YYYY	

Pregnancy Prevention

The patient has been etsablished on one of the following for at least 4 weeks	
Implant	Tick
Levonorgestrel-releasing intrauterine system (US)	Tick
Medroxyprogesterone acetate depot	Tick
Tubal sterilisation	Tick

Sexual intercourse with a vasectomised partner only; vasectomy must be confirmed by two negative semen analyses	Tick
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	Tick
Committed to complete and absolute abstinence	Tick

Pregnancy Test

Date of last negative pregnancy test	DD	MM	YYYY

Prescriber Confirmation

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 will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

Prescriber First Name				
Prescriber Last Name				
Prescriber Signature		Date	DD	MM	YYYY

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that severe birth defects are expected to 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.	Patient initials
I understand that I must not take lenalidomide if I am pregnant or plan to become pregnant	Patient initials
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 the 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.	Patient initials
I understand that if I need to change or stop my method of contraception, I will discuss this first with the prescriber prescribing my contraception and the prescriber prescribing lenalidomide.	Patient initials
I understand that before starting the lenalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilization, 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.	Patient initials
I understand that I must immediately stop taking lenalidomide and inform my prescriber if I become pregnant while taking this drug; or if I miss my menstrual period or experience any unusual menstrual bleeding, or think FOR ANY REASON that I may be pregnant.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials

I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I understand that even if I have amenorrhoea I must comply with advice on contraception.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	Patient initials
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.	Patient initials
I understand 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, the distributor for the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	Patient initials

Patient Confirmation

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.

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.

Should you have any queries in relation to the use of your personal data please contact the Marketing Authorisation Holder.

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.

Signed		Name (print)		Date	DD	MM	YYYY

Lenalidomide Pregnancy Prevention Programme (PPP)

Woman of Non-Childbearing Potential Treatment Initiation Form

Treatment Initiation Form for counselling the patient to ensure the patient is fully informed about the safe use of lenalidomide.

This Treatment Initiation Form is to assist you with counselling a patient before they commence lenalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each woman of non-childbearing potential prior to the initiation of their lenalidomide treatment.

The purpose 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 drug reactions associated with the use of lenalidomide. It is mandatory that woman of non-childbearing potential receive counselling and education to be made aware of the risks of lenalidomide.

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of foetal exposure.

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 name																							
Patient Last name																							
Date of Birth	DD	MM	YYYY		Counselling Date	DD	MM	YYYY															

Prescriber Confirmation

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 will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

Prescriber First Name																							
Prescriber Last Name																							
Prescriber Signature																Date	DD	MM	YYYY				

Patient: Please read thoroughly and initial the adjacent box if you agree with the statement

I understand that severe birth defects are expected to 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.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Guide and understand the contents, including the information about other Possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment	Patient initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of the treatment	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	Patient initials
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	Patient initials
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 Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	Patient initials

Patient Confirmation

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

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 packaging 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.

Should you have any queries in relation to the use of your personal data please contact the Marketing Authorisation Holder.

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.

Signed		Name (print)		Date	DD	MM	YYYY

Lenalidomide Prescription Authorisation Form

Completion of this information is mandatory for ALL patients. A newly completed copy of this form must accompany EVERY lenalidomide prescription. 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 name: (print)

Indication (tick)

- Multiple myeloma ☐
- Mantle cell lymphoma relapsed and/or refractory ☐
- Myelodysplastic syndromes with isolated del5qcytogenetic abnormality ☐
- Follicular lymphoma ☐
- Other (please specify) ☐

Capsule strength prescribed: (tick) 2.5mg☐ 5mg☐ 7.5mg ☐ 10mg☐ 15mg☐ 20mg ☐ 25mg☐ ☐

Quantity of **Capsules** prescribed: *
* Do **NOT** enter number of packs

Enter the cycle number(s) prescribed for this patient

Please tick all boxes that apply

Woman of non-childbearing potential Yes☐ No☐

Male Yes☐ No☐

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). Yes☐ No☐

Note to pharmacist – Do not dispense unless ticked YES for Male patients

Woman of childbearing potential Yes☐ No☐

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. Yes☐ No☐

Date of last negative pregnancy test: ☐

Note to pharmacist – Do not dispense unless ticked yes and a negative test has been conducted within 3 days prior to 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 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	Bleep

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, the dispensing will be taking place within 7 days of the date of prescription. I am dispensing no more than a 4 week supply to women of childbearing potential and 12 weeks for males and women of non- childbearing potential

Sign	Print
Date	Bleep

Name and postcode 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 a Lenalidomide Pregnancy Prevention Programme and subsequently be able to order and dispense lenalidomide to your patient.

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

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

Fax to Nominated Pharmacy

Fax Number: _____

Nominated Pharmacy Name and Address: (Please print)

_____

_____

_____

Date Faxed: Time Faxed:

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 chose to dispense Lenalidomide Rowex, you must register with Rowex Ltd. Please contact Rowex on 1800 304 400 and Rowex will forward you the relevant information.

If you have any questions regarding this form or require further information about lenalidomide please contact Rowex Ltd. Risk management on 027 50077 and ask for the PV Department.

Pharmacy Registration Form

You will need to complete the relevant registration form in order to obtain lenalidomide.

Lenalidomide

Lenalidomide Rowex (lenalidomide) Pharmacy Registration Form – Part I

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 minimization procedures when dealing with prescriptions for lenalidomide as specified by Rowex Ltd, in the Lenalidomide Rowex Healthcare Professional's Information Pack.

1.	I have read and understood the Lenalidomide Rowex Healthcare Professional's Information Pack	TICK
2.	All pharmacists who dispense Lenalidomide Rowex will have read and understood the lenalidomide Healthcare Professional's information pack	TICK
3.	If supplied with Lenalidomide Rowex, it will only be used for the purpose of dispensing the product by the Pregnancy Prevention Programme registered pharmacy to the patient	TICK
4.	Lenalidomide Rowex will be dispensed, checked and stored according to our standard documented procedures for oral anti-cancer medicines.	TICK
5.	Prescriptions for Lenalidomide Rowex will be dispensed only if accompanied by a completed lenalidomide Prescription Authorization Form.	TICK
6.	The pharmacist dispensing Lenalidomide Rowex will check each prescription and Prescription Authorization Form for completeness and countersign the authorization form prior to dispensing.	TICK
7.	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-child bearing potential.	TICK
8.	Dispensing of Lenalidomide Rowex to women of childbearing potential should occur within 7 days of the prescription	TICK
9.	After dispensing, lenalidomide Prescription Authorization Forms will be kept in pharmacy for a minimum of 2 years.	TICK
10.	Pharmacies must undertake the mandatory annual self-audit of the PAFs	TICK
11.	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 Rowex so that their obligation to report to the regulatory agencies on the overall effectiveness of the programme can be met.	TICK
12	I will notify Rowex of any change in contact details.	TICK

I understand that registration to obtain and supply Lenalidomide Rowex will only be granted if I agree to items 1–12 described above as supply of Lenalidomide Rowex 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 minimization procedures by completing this form and sending to the Rowex.

Sign:
Print:

Date: DD MM YYY

Fax the completed forms to Rowex on 027 50417 or email to pv@rowa-pharma.ie

Lenalidomide Rowex (lenalidomide) Pharmacy Registration Form – Part II
If you would like to register additional pharmacy sites to be covered by your registration please provide details below.

Institution name:

Additional pharmacy sites covered by registration with Rowex to supply Lenalidomide Rowex.

Name of Hospital/Pharmacy:	
Delivery Address:	Invoice Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Name of Hospital/Pharmacy:	
Delivery Address:	Invoice Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Name of Hospital/Pharmacy:	
Delivery Address:	Invoice Address (if different):
Tel:	Tel:
Fax:	Fax:
Email:	Email:

Fax the completed forms to Rowex on 027 50417 or email to pv@rowa-pharma.ie

ROWEX

UDD ORDERS ONLY

Version 2 - CCF 26191 Date of approval: Nov 2023

Lenalidomide Rowex® (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 the next working day (note there are no deliveries on Saturdays).

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

Ordered by: (Please print full name and position e.g. Irish registered pharmacist/technician)

Pharmacy Name & address: (Please print)

Pharmacy Stamp

Pharmacy Telephone:

Please indicate your nominated United Drug routine wholesaler: (Please tick)

UD	Dublin		Ballina		Limerick	

Patient Details

Prescriber (Please print)

Treating Hospital

Indication

Patient Date of Birth

Male

Woman of childbearing potential (WCBP)

Woman of non-childbearing potential (WNCBP)

Dose of lenalidomide being prescribed

Date of prescription

Product Description	Strength	Quantity required
Lenalidomide Capsules	5mg	
Lenalidomide Capsules	10mg	
Lenalidomide Capsules	15mg	
Lenalidomide Capsules	25mg	
Comments		

I confirm that I am ordering on behalf of a registered pharmacy and that lenalidomide will be dispensed in accordance with the risk minimisation procedures for lenalidomide, as specified by Rowex Ltd in the Lenalidomide Rowex Healthcare Professional's Information Pack.

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 child bearing potential dispensing will be within 7 days of the date of prescription

Sign

Date

Telephone

Print

FOR INTERNAL USE ONLY:

Sales Order: _____ Date: _____ Initials: _____ Tracker number: _____

ROWEX

UNIPHAR ORDERS ONLY

Version 2 - CCF26191 Date of approval: Nov 2023

Lenalidomide Rowex® (lenalidomide) Order Form Ireland

Orders cannot be processed unless this form is fully completed and signed. The completed Order Form should be emailed to Rowex Ltd. for the attention of Rowex Customer Service **SpecialOrders@rowa-pharma.ie** or **faxed** to 027 50417. Orders received before **13.30 Monday to Friday** will be delivered the next working day (note there are no deliveries on Saturdays).

For queries about your order please email **SpecialOrders@rowa-pharma.ie** or **Telephone 027 50077.** Please ensure all data is recorded in Black or Blue ink. Prescription Authorisation Forms and prescriptions should not be sent to Rowex Ltd.

Pharmacy Details

Ordered by: (Please print full name and position e.g. Irish registered pharmacist/technician)

Pharmacy Name & address: (Please print)

Pharmacy Stamp

Pharmacy Telephone:

Pharmacy GMS code:

Patient Details

Prescriber (Please print)

Treating Hospital

Indication

Patient Date of Birth

Male

Woman of childbearing potential (WCBP)

Woman of non-childbearing potential (WNCBP)

Dose of lenalidomide being prescribed

Date of prescription

Product Description	Strength	Quantity required
Lenalidomide Capsules	5mg	
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Lenalidomide Capsules	15mg	
Lenalidomide Capsules	25mg	
Comments		

I confirm that I am ordering on behalf of a registered pharmacy and that lenalidomide will be dispensed in accordance with the risk minimisation procedures for lenalidomide, as specified by Rowex Ltd in the Lenalidomide Rowex Healthcare Professional's Information Pack.

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 child bearing potential dispensing will be within 7 days of the date of prescription

Sign

Date

Telephone

Print

FOR INTERNAL USE ONLY:

Sales Order: _____ Date: _____ Initials: _____ Tracker number: _____

Pregnancy Reporting Form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with lenalidomide.

As part of Rowex Ltd's Safety Monitoring System, it is essential that we follow-up on all reported pregnancies. Rowex Ltd. will therefore be in contact with you for further information in due course and would value your co-operation to ensure we are able to obtain all relevant information regarding fetal exposure to lenalidomide.

Please email immediately to Rowex Ltd. at the number/address below:

Rowex Ltd. Drug Safety: Tel: 027 50077 Rowex Ltd.
Email: pv@rowa-pharma.ie Bantry, Co. Cork.

Reporter's details		
Title: (Mr, Mrs, Miss, Dr., etc)	First Name(s):	Surname:
Job Title:		
Address:		
City, Town:	County:	
Post code:	Country:	
Phone Number:	Fax Number:	
Email address:		

Female Patient information		
Patient ID:	Age:	Date of birth: DD MM YYYY

Female partner or male patient information		
Patient ID:	Age:	Date of birth: DD MM YYYY

Exposure of a pregnant female - not patient or partner		
Patient ID:	Age:	Date of birth: DD MM YYYY

Patient treatment information: Lenalidomide capsule			
Batch No.:	Expiry Date:	Dose:	Frequency:
Start Date: DD MM YYYY	Stop Date: DD MM YYYY		
Indication for use:			

Menses information				
Date of last menses: DD MM YYYY	Regular menses: No?	TICK	Regular menses: Yes?	TICK

Pregnancy information				
Has the pregnancy been confirmed?	No?	TICK	Yes?	TICK
Estimated gestational stage:	Estimated date of delivery: DD MM YYYY			
Has the patient already been referred to an obstetrician/gynecologist?	No?	TICK	Yes?	TICK

If yes, please specify his/her name and contact details

Name:	Contact:
Reporter	
Signature:	Date: DD MM YYYY

Background Information on Reason for Pregnancy

	YES	NO
Was patient erroneously considered not to be of child bearing potential	TICK	TICK
If yes, state reason for considering not to be of childbearing potential	TICK	TICK
a. Age ≥ 50 years and naturally amenorrheic* for ≥ 1 year *amenorrhea following cancer therapy or during lactation does not rule out childbearing potential	TICK	TICK
b. Premature ovarian failure confirmed by a specialist gynecologist	TICK	TICK
c. Previous bilateral salpingo-oophorectomy, or hysterectomy	TICK	TICK
d. XY genotype, Turner syndrome, uterine agenesis.	TICK	TICK

Indicate from the list below what contraception was used		
a. Implant	TICK	TICK
b. Levonorgestrel-releasing intrauterine system (IUS)	TICK	TICK
c. Medroxyprogesterone acetate depot	TICK	TICK
d. Tubal sterilization (specify below)	TICK	TICK
I. Tubal ligation	TICK	TICK
II.Tubal diathermy	TICK	TICK
III. Tubal clips	TICK	TICK
e. Sexual intercourse with a vasectomized male partner only; vasectomy must be confirmed by two negative semen analyses	TICK	TICK
f. Ovulation inhibitory progesterone-only pills (i.e., desogestrel)	TICK	TICK
g. Other progesterone-only pills	TICK	TICK
h. Combined oral contraceptive pill	TICK	TICK
i. Other intra-uterine devices	TICK	TICK
j. Condoms	TICK	TICK
k. Cervical cap	TICK	TICK
l. Sponge	TICK	TICK
m.Withdrawal	TICK	TICK
n. Other	TICK	TICK
o. None	TICK	TICK

Indicate from the list below the reason for contraceptive failure		
Missed oral contraception	TICK	TICK
Other medication or intercurrent illness interacting with oral contraception	TICK	TICK
Identified mishap with barrier method	TICK	TICK
Unknown	TICK	TICK
Had the patient committed to complete and continuous abstinence	TICK	TICK
Was lenalidomide started despite patient already being pregnant	TICK	TICK
Did patient receive educational materials on the potential risk of teratogenicity	TICK	TICK
Did patient receive instructions on need to avoid pregnancy	TICK	TICK

Prenatal information		
Date of last menstrual period: DD MM YYYY	Estimated Delivery Date: DD MM YYYY	
PREGNANCY TEST	REFERENCE RANGE	DATE
Urine Qualitative:		DD MM YYYY
Serum Quantitative:		DD MM YYYY

Past obstretric history						
Year of pregnancy	Outcome					
	Spontaneous abortion	Therapeutic abortion	Live birth	Still birth	Gestational age	Type of delivery

Birth defects	Yes	No	Unknown
Was there any birth defect from any pregnancy			
Is there any family history of any congenital abnormality abstinence			
If yes to either of these questions, please provide details below:			

Maternal past medical history				
Condition	Dates		Treatment	Outcome
	From	To		

Maternal current medical conditions		
Condition	From	Treatment

Maternal social history	Yes	No
Alcohol	TICK	TICK
If yes, amount/units per day:		
Tobacco	TICK	TICK
If yes, amount per day:		
IV or recreational drug use	TICK	TICK
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

Name of person completing this form	Signature	Date

Data Privacy statement:
All personal information will be strictly confidential and not used for any other purposes than preparing a report form.

Lenalidomide

Adverse Event Report Form

(Adverse Event Report Form related to Lenalidomide EU RMP version 2.2)

Reporter's details		
Title: (Mr, Mrs, Miss, Dr, etc)	First Name(s):	Surname:
Job Title:		
Address:		
City, Town:	Country:	
Post code:	Country:	
Phone Number:	Fax Number:	
Email address:		

Patient information		
Patient ID (initials):	Age:	Date of birth: DD MM YYYY
Weight (Kg):		Height (cm):

Adverse event	
Overall diagnosis of the event	Event onset date: DD MM YYYY
	Event stop date: DD MM YYYY
	Or ongoing at time of reporting (if less than 24 hours) HR MIN

Description of adverse event	**Outcome of adverse event**	
Symptoms and treatment	Recovered	TICK ☐
	Recovered with sequele	TICK ☐
	Not recovered	TICK ☐
	Unknown	TICK ☐
	Death	TICK ☐
	Date of death	DD MM YYYY
	Possible cause of death	

If autopsy is performed please forward report. Please attach relevant clinical laboratory assessments to confirm the event.

Seriousness of adverse event (tick all that apply)	
Death	☐
Life-threatening	☐
Hospitalization or prolonged hospitalization	☐

Company

Address

City, Town

Country

Persistent or significant disability or incapacity	☐
Congenital anomaly/birth defect	☐
Other medically important condition or event	☐
Non-serious	☐

Tel:
Fax:
Email:

Medical history (May be supplied as a copy of Medical file if up to date)		
Current or past relevant medical history (including concurrent illness, allergy, smoking, alcohol abuse)	YES ☐	NO ☐
If YES please specify		

Suspect drug						
Drug, Dosage-form, Strength, Route (e.g. Tab 5mg, oral)	Dose & frequency	Batch no.	Therapy Start date	Therapy Stop date	Causal relationship 1= Not related 2 = Related	Indication for use of drug
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		

Other medication (Medication taken during the past 3 months prior to the event - May be supplied as a copy of Medical file if up to date)						
Drug, Dosage-form, Strength, Route (e.g. Tab 5mg, oral)	Dose & frequency	Batch no.	Therapy Start date	Therapy Stop date	Causal relationship 1= Not related 2 = Related	Indication for use of drug
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		
			DD MM YY	DD MM YY		

Action taken, suspect drug							
Continued unchanged	☐	Continued, dose or dose regimen changed	☐	Withdrawn	☐	N/A	☐
Please specify if dose or dose regimen changed:							

Notification					
Initial report	☐	Final report	☐	Follow-up report	☐
Name:					
Title:					

Signature:

Data Privacy statement:

All personal information will be strictly confidential and not used for any other purposes than preparing a report form.