Lenalidomida Generis

Lenalidomide▼

Healthcare Professional's Information Pack

Important Safety Information:

Healthcare Professionals involved in the prescribing or dispensing of Lenalidomide must read and understand the information contained within this pack.

For complete safety information please refer to the Summary of Product Characteristics (SmPC). These documents can also be found at https://medicinesauthority.gov.mt/rmm.

Lenalidomida Generis

Lenalidomide▼

Important Forms

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Combined Prescriber Checklist

Date of preparation of text: October 27th, 2023

Eugia Pharma (Malta) Ltd.

Approved by Malta Medicines Authority: January 29th, 2024

Lenalidomida Generis (lenalidomide) ▼

Health care Professional's Information Pack

This pack contains the information and materials needed for the prescribing and dispensing of Lenalidomida Generis (lenalidomide), including information about the Pregnancy Prevention Programme.

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

An easy reference guide is included at the back of your pack. This summarises the information for ongoing patient safety and the main steps in the Lenalidomide Pregnancy Prevention Programme process.

Lenalidomide is indicated:

- As monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.
- As combination therapy with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
- In combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.
- As monotherapy for the treatment of adult patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.
- As monotherapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
- In combination with rituximab (anti-CD20 antibody), 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.

Lenalidomide is structurally related to thalidomide, a known human teratogenic 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. Lenalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this pack are carried out.

Information for Healthcare Professionals
This section contains information for healthcare professionals prescribing or dispensing Lenalidomida Generis (lenalidomide).

Information for Healthcare Professionals

Information for Patients
This section contains information about Lenalidomida Generis (lenalidomide) that you should give to your patients.

Risk Awareness Forms
There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete the relevant form before prescribing Lenalidomida Generis (lenalidomide) to your patients.

Adverse Event and Pregnancy Reporting Forms
Please report Adverse Events, suspected and confirmed pregnancies, and foetal exposure. This section contains forms you can use.

Treatment Checklists

Lenalidomida Generis

Lenalidomide ▼

Pregnancy Prevention Programme

Information for Healthcare Professionals

Prescribing or Dispensing Lenalidomide

This brochure contains the information needed for the prescribing and dispensing of Lenalidomida Generis (lenalidomide), including information about the Pregnancy Prevention Programme (PPP). Please also refer to the Summary of Product Characteristics (SmPC).

LENALIDOMIDE 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.

Other side effects of Lenalidomide:
Please refer to the Lenalidomide SmPC for full information regarding all side effects and recommended precautions.

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

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

To ensure your patients' health and safety, please read this brochure 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 Risk Awareness Form, before starting treatment.

Contents

1. Introduction

Lenalidomide is an immunomodulating medicinal product.

Two Phase III clinical studies assessed Lenalidomide maintenance in patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT) was assessed in (CALGB 100104 and IFM 2005 02).

In Study CALGB 100104, patients were randomised 1:1 within 90 to 100 days after ASCT to receive either Lenalidomide or placebo maintenance. The maintenance dose was 10 mg once daily on Days 1 to 28 of repeated 28- day cycles (increased up to 15 mg once daily after 3 months in the absence of dose limiting toxicity), and treatment was continued until disease progression.

The results of progression free survival (PFS) at unblinding (cut-off of 17 December 2009) showed a 62% reduction in risk of disease progression or death favouring Lenalidomide over placebo. The Hazard Ratio was 0.38 (95% CI 0.27, 0.54; p <0.001). The median overall PFS was 33.9 months (95% CI not evaluable [NE], NE) in the Lenalidomide arm versus 19.0 months (95% CI 16.2, 25.6) in the placebo arm. The updated PFS, using a cut-off of 01 February 2016, continued to show a PFS advantage for Lenalidomide (Hazard Ratio = 0.61; p <0.001).

In Study IFM 2005-02, patients who had undergone ASCT and had achieved at least a stable disease response at the time of haematologic recovery were randomised 1:1 to receive either Lenalidomide or placebo maintenance (10 mg once daily on Days 1 to 28 of repeated 28-day cycles increased up to 15 mg once daily after 3 months in the absence of dose-limiting toxicity) following 2 courses of Lenalidomide consolidation (25 mg/day, Days 1 to 21 of a 28- day cycle). Treatment was to be continued until disease progression. The study was unblinded upon the recommendations of the data monitoring committee after surpassing the threshold for a preplanned interim analysis of PFS. After unblinding, patients receiving placebo were not crossed over to Lenalidomide therapy prior to progressive disease. The Lenalidomide arm was discontinued, as a proactive safety measure, after observing an imbalance of Second Primary Malignancies (SPM). The results of PFS at unblinding, following a preplanned interim analysis, using a cut-off of 07 July 2010 (31.4 months follow up) showed a 48% reduction in risk of disease progression or death favoring Lenalidomide over placebo. The Hazard Ratio was 0.52 (95% CI 0.41, 0.66; p <0.001). The median overall PFS was 40.1 months (95% CI 35.7, 42.4) in the Lenalidomide arm versus 22.8 months (95% CI 20.7, 27.4) in the placebo arm. The updated PFS, using a cut-off of 01 February 2016 (96.7 months follow-up) continued to show a PFS advantage for Lenalidomide (Hazard Ratio = 0.57; p <0.001).

A Phase III clinical study in newly diagnosed multiple myeloma (MM-020) compared Lenalidomide and dexamethasone (Rd) given for 2 different durations of time (i.e. until progressive disease [Arm Rd] or for up to eighteen 28-day cycles [72 weeks, Arm Rd18]) to that of melphalan, prednisone and thalidomide (MPT) for a maximum of twelve 42-day cycles (72 weeks). The study showed a statistically significant prolongation of PFS benefit in patients receiving Rd compared to MPT. The Hazard Ratio was 0.69 (p <0.001).

Another Phase III study in newly diagnosed multiple myeloma (MM-015) was conducted to evaluate the safety and efficacy of Lenalidomide in combination with melphalan and prednisone (MPR) with or without Lenalidomide maintenance therapy until disease progression, to that of melphalan and prednisone for a maximum of 9 cycles.

The study showed a statistically significant prolongation of PFS benefit in patients receiving MPR+R compared to MPp+p (melphalan, prednisone, placebo + placebo maintenance). The Hazard Ratio was 0.37 (p <0.001).*

In Phase III clinical studies in multiple myeloma with at least one prior therapy, the median time to progression (TTP) was 60.1 weeks in patients treated with Lenalidomide/dexamethasone versus 20.1 weeks in patients treated with placebo/dexamethasone. The median PFS was 48.1 weeks in patients treated with Lenalidomide/dexamethasone versus 20.0 weeks in patients treated with placebo/-dexamethasone.*

In a Phase III clinical study in myelodysplastic syndromes (MDS-004), a significant larger proportion of patients achieved the primary endpoint of transfusion independence (>182 days) on Lenalidomide 10 mg compared with placebo (55.1% vs. 6.0%). The median time to transfusion independence in the Lenalidomide 10 mg arm was 4.6 weeks. The median duration of transfusion independence was not reached in any of the treatment arms, but should exceed 2 years for the Lenalidomide-treated subjects. The median increase in haemoglobin (Hgb) from baseline in the 10 mg arm was 6.4 g/dL.*

In a phase II study of Lenalidomide (N=170) versus single agent of investigator's choice of monotherapy with either chlorambucil, cytarabine, rituximab, fludarabine, or gemcitabine (N=84) in patients with mantle cell lymphoma (MCL) who were refractory to their last regimen or had relapsed one to three times (Study MCL-002), median PFS was significantly improved for Lenalidomide versus investigator's choice (37.6 versus 22.7 weeks; Hazard Ratio = 0.61, p= 0.004).*

*text according to SmPC

1.1 Licensed Indication

Lenalidomide is an immunomodulating medicinal product.

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

AND

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

AND

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

AND

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

AND

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

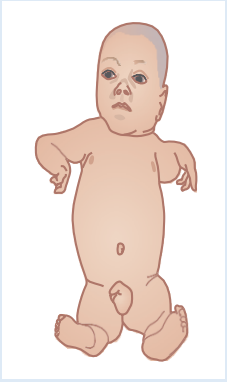
AND

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

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

1.2 Lenalidomide Pregnancy Prevention Programme

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.



- All men and all women of childbearing potential should undergo, at treatment initiation, counselling of the need to avoid pregnancy (this must be documented via a Risk Awareness Form and checklists for counselling are provided with this pack)
- It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood this brochure before prescribing or dispensing Lenalidomide for any patient
- The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in the attached Algorithm
- Patients should be capable of complying with the requirements of safe use of Lenalidomide
- Patients must be provided with the appropriate Patient Brochure and Risk Awareness Form

All of the Lenalidomide Pregnancy Prevention Programme materials are contained within the "Healthcare Professional's Information Pack" and additional copies can be obtained by using the contact details displayed on the front of this brochure.

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

The following are core requirements of the Pregnancy Prevention Programme:

- A controlled distribution system
- All healthcare professionals dispensing or prescribing Lenalidomide must read the Lenalidomide Healthcare Professional's Information Pack

2. Therapeutic Management Advice to Avoid Foetal Exposure

2.1 Women of Non-childbearing Potential

Women in the following groups are considered **not** to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice;

- Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year. Please note amenorrhoea following cancer therapy or during breastfeeding 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 Women of Childbearing Potential

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

- Pregnant
- A woman who is 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 should be avoided.

- Women of childbearing potential (even if they have amenorrhoea) must:
  - use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after Lenalidomide therapy, and even in case of dose interruption or
  - commit to absolute and continuous abstinence confirmed on a monthly basis

AND

- have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/mL) once she has been established on contraception for at least 4 weeks, at least in 4-weekly intervals during therapy (this includes dose interruptions) and at least 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This includes those women of childbearing potential who confirm absolute and continued sexual abstinence.

Patients should be advised to inform the healthcare professional 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.

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

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

The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by

two negative semen analyses

- Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

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

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

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

Your patient should be advised that if a pregnancy does occur whilst she is receiving Lenalidomide, she must stop treatment immediately and immediately inform her prescriber

Requirements in the event of a suspected pregnancy while on treatment with Lenalidomide:
- Stop treatment immediately - Refer the patient to a physician specialised or experienced in teratology for evaluation and advice.
- Notify MAH immediately of all such occurrences by contacting Eugia Pharma (Malta) Ltd (Tel: +356 22294000; Email: eupvg@eugiapharma.com). Please also complete the Pregnancy Reporting Form included in this pack. MAH will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.

2.3 Men

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

Inform your patient which are the effective contraceptive methods that his female partner can use.

Lenalidomide is present in semen. Therefore, all male patients should use condoms throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment if

their partner is pregnant or of childbearing potential who is not using effective contraception and even if the male patient has undergone vasectomy.

Patients should be instructed that if their partner does become pregnant 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 becomes pregnant, then he must inform his prescriber immediately, then:
Refer the female partner to a physician specialised or experienced in dealing with teratology for advice and evaluation.
Notify MAH immediately by contacting Eugia Pharma (Malta) Ltd. (Tel: +356 22294000; Email: eupvg@eugiapharma.com). Please also complete the Pregnancy Reporting Form included in this pack.
MAH will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.

2.4 Advice to all Patients

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

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.

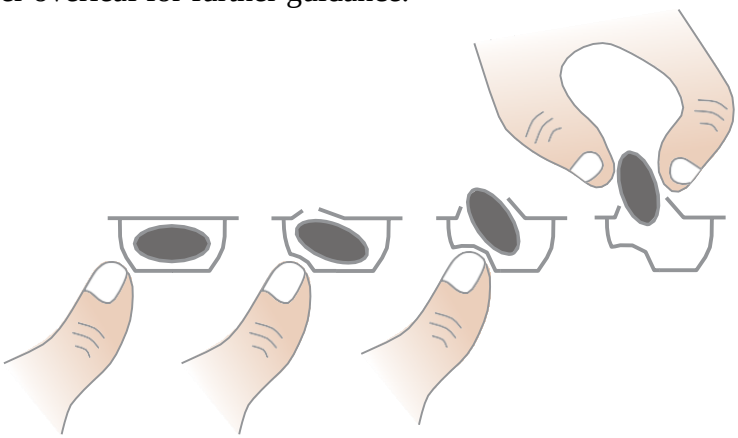
It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

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. Refer below for further guidance.

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.

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. Refer overleaf for further guidance.



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

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
- Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule)
- Use proper technique when removing gloves to prevent potential skin exposure (see 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 MAH Eugia Pharma (Malta) Ltd. (Tel: +356 22294000; Email: eupvg@eugiapharma.com).

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.

2.4.2 Blood Donation

Patients should not donate blood during treatment and for at least 7 days after cessation of treatment with lenalidomide.

2.5 Prescribing Lenalidomide

2.5.1 Maximum Prescription Lengths

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

2.5.2 Initial Prescription

Prescribers wishing to prescribe Lenalidomide must confirm their understanding of the risk minimisation Pregnancy Prevention Programme Eugia Pharma (Malta) Ltd.

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of Lenalidomide in accordance with the measures described in this brochure and the SmPC.
- Obtain their written confirmation (using the correct Risk Awareness Form) that they have received and understood this information and provide the patient with a copy.
- Ensure that your patient is using the appropriate method of contraception, if relevant.
- Ensure that your patient is using effective contraception (if appropriate).

2.6 Dispensing Lenalidomide

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

For males and women of non-childbearing potential, prescriptions of Lenalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription.

2.6.1 Dispensing Advice

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

- 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, according to local requirements.

4. Posology

4.1 Newly Diagnosed Multiple Myeloma

4.1.1 Lenalidomide Maintenance in Patients who have Undergone Autologous Stem Cell Transplantation (ASCT)

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.

4.1.2 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.

4.1.3 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.

4.1.4 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.

4.2 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.

4.3 Myelodysplastic Syndromes

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

4.4 Mantle Cell Lymphoma

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

4.5 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.

5. Selected Risks of Lenalidomide

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

5.1 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 ≤ 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.

5.2 Second Primary Malignancies

The risk of occurrence of Second Primary Malignancies (SPM) must be taken into account before initiating treatment with Lenalidomide either in combination with melphalan or immediately following

high dose melphalan and ASCT. Prescribers should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated.

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

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

5.3 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).

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

The safe use of Lenalidomide is of paramount importance.

Adverse Events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Adverse Event Report forms and Pregnancy Reporting forms are included in this pack and should be forwarded to Eugia Pharma (Malta) Ltd. (Tel: +356 22294000; Email: eupvg@eugiapharma.com).

You should also report side effects directly via the national reporting system to

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
Email: postlicensing.medicinesauthority@gov.mt

Or

ADR Reporting: www.medicinesauthority.gov.mt/adrportal

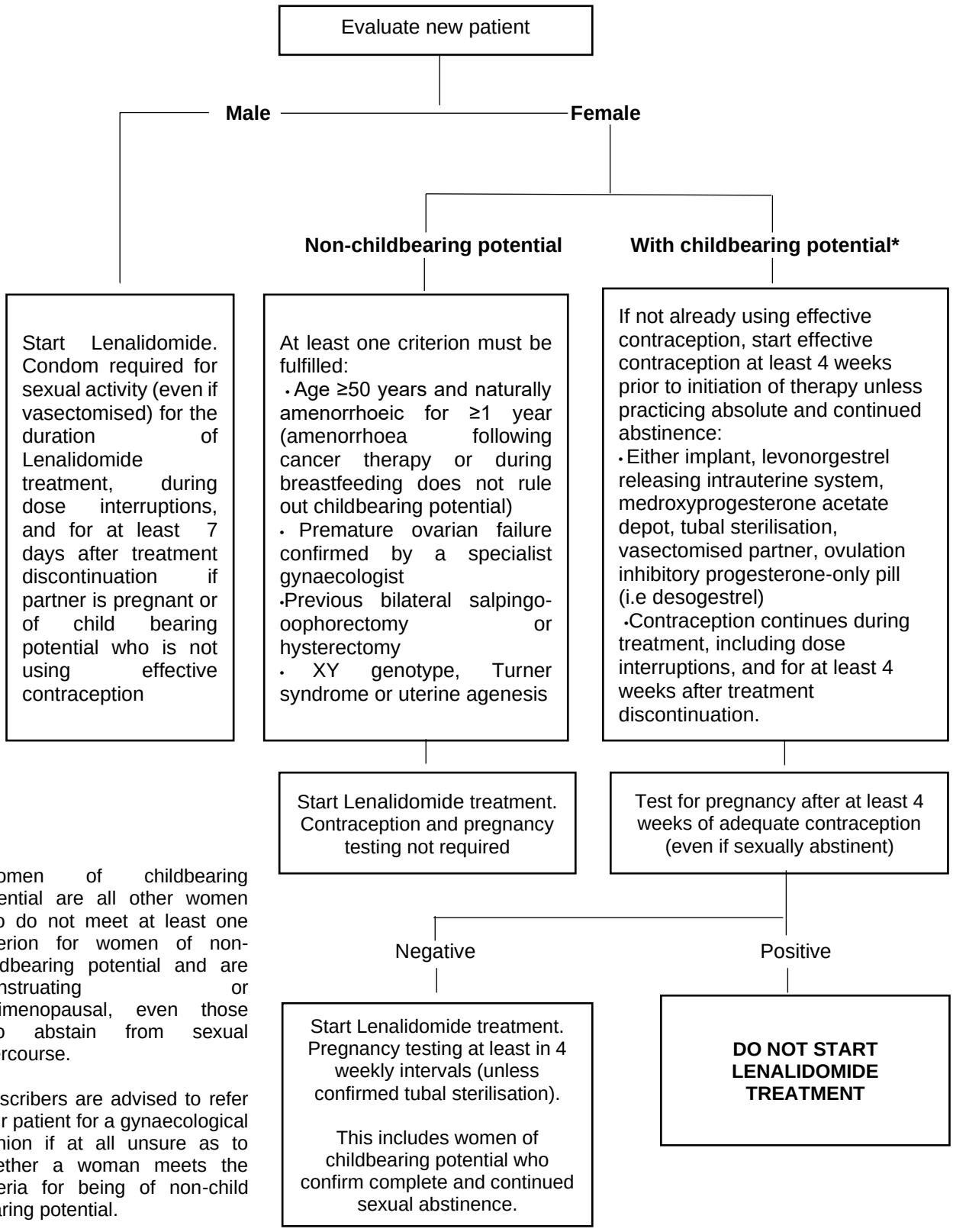
AND/OR

Marketing Authorization Holder: Eugia Pharma (Malta) Ltd - Vault 14, Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta
Contact: +356 22294000
Email: eupvg@eugiapharma.com

Distributor in the Source Country: Generis Farmacêutica, S.A. - Rua João de Deus, 19, 2700-487, Amadora
Contact: +351 219849300
Email: pharmacovigilance.portugal@aurobindo.com

Local Distributor: Cherubino Limited - DELF Building, Sliema Road, Gzira, GZR 1637, Malta
Contact: +356 21343270
Email: pharmacovigilance@cherubino.com.mt

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



*Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential and 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-child bearing potential.

8. Contact Details

For information and questions on the Risk Management of Eugia Pharma (Malta) Ltd.'s products and the Pregnancy Prevention Programme.
Tel: +356 22294000
Email: eupvg@eugiapharma.com
Cc: pharmacovigilance.portugal@aurobindo.com

Medical Information:

To report any Adverse Events or suspected pregnancies, or to obtain Medical Information on Eugia Pharma (Malta) Ltd.'s products.
Tel: +356 22294000
Email: euvpg@eugiapharma.com

You should also report side effects directly via the national reporting system to

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
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Marketing Authorization Holder: Eugia Pharma (Malta) Ltd. - Vault 14, Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta
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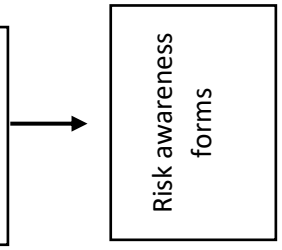
Local Distributor: Cherubino Limited - DELF Building, Sliema Road, Gzira, GZR 1637, Malta
Contact: +356 21343270
Email: pharmacovigilance@cherubino.com.mt

Risk Awareness Forms

There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete the relevant form before prescribing Lenalidomida Generis (lenalidomide) to your patients.



Lenalidomida Generis

Lenalidomide▼

Pregnancy Prevention Programme (PPP)

Woman of Childbearing Potential Risk Awareness Form

Introduction

This Risk Awareness Form must be completed for each female patient of childbearing potential prior to the initiation of their Lenalidomida Generis (lenalidomide) treatment. The form should be retained with their medical records, and a copy provided to the patient.

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

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

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 Preparation

The patient has been established on one of the following for at least 4 weeks	
Implant	TICK
Levonorgestrel-releasing intrauterine System (IUS)	TICK
Medroxyprogesterone acetate depot	TICK
Tubal Sterilization	TICK
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analysis	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

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

Prescriber 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 physician prescribing my contraception and the physician prescribing my 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 sterilisation, I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	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 Brochure 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 the 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 pharmacist at the end of my treatment.	Patient initials

I understand that even in have amenorrhoea I must comply with the advice on contraception.	Patient initials

I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during the treatment 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.

Personal data is used solely for the purpose of entering you into the Pregnancy Prevention Programme and is processed by Eugia Pharma (Malta) Ltd, as marketing authorisation holder of pharmaceutical products and its worldwide Affiliates, to the extent and for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact us at email: dpo@aurobindo.com.

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

Lenalidomida Generis

Lenalidomide ▼

Pregnancy Prevention Programme (PPP)

Woman of Non-Childbearing Potential Risk Awareness Form

Introduction

This Risk Awareness Form must be completed for each woman of non-childbearing potential prior to the initiation of their Lenalidomida Generis (lenalidomide) treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that women of non-childbearing potential receive counselling and education to be made aware of the risks of lenalidomide.

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

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 Brochure 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 the 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 have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during the treatment 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.

Personal data is used solely for the purpose of entering you into the Pregnancy Prevention Programme and is processed by Eugia Pharma (Malta) Ltd., as marketing authorisation holder of pharmaceutical products and its worldwide Affiliates, to the extent and for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact us at email: dpo@aurobindo.com.

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

Lenalidomida Generis

Lenalidomide ▼

Pregnancy Prevention Programme (PPP)

Male Treatment Risk Awareness Form

Introduction

This Risk Awareness Form must be completed for each male patient prior to the initiation of their Lenalidomida Generis (lenalidomide) treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that males receive counselling and education to be made aware of the risks of Lenalidomide.

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

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 women 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

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

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 Brochure 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) 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 the treatment 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.

Personal data is used solely for the purpose of entering you into the Pregnancy Prevention Programme and is processed by Eugia Pharma (Malta) Ltd., as marketing authorisation holder of pharmaceutical products and its worldwide Affiliates, to the extent and for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact us at email: dpo@aurobindo.com.

Patient Signature	

Date:	DD	MM	YYYY

Adverse Event and Pregnancy Reporting Forms

Please report Adverse Events, suspected and confirmed pregnancies, and foetal exposure. This section contains forms you can use.

Lenalidomida Generis (lenalidomide)

Pregnancy Report Form

Pregnancy reports must be sent to Eugia Pharma (Malta) Ltd. IMMEDIATELY

This form must be returned to Eugia Pharma (Malta) Ltd.

Tel: +356 22294000, Email: eupvg@eugiapharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Date of awareness:	D	D	M	O	N	Y	Y	Y	Y

Patient Data

Sex of Patient	○ Female ○ Male

- Pregnancy of Patient
- Pregnancy of Patient's Partner OR
- Exposure of a Pregnant Female (complete information below)

Pregnant Woman's Initials (F, M, L):			

Date of Birth:	D	D	M	O	N	Y	Y	Y	Y

Age	

Patient Initials (F, M, L): (Who received drug)			

Age	

Date of Birth:	D	D	M	O	N	Y	Y	Y	Y

Drug Name:	

Date of First Dose:	D	D	M	O	N	Y	Y	Y	Y

Date of Last Dose:	D	D	M	O	N	Y	Y	Y	Y

Pregnancy Initially Diagnosed By:

- ○ Home Urine Test
- ○ Office Urine Test
- ○ Serum Test

Date of pregnancy Test:	D	D	M	O	N	Y	Y	Y	Y

Last Menstrual Period:	D	D	M	O	N	Y	Y	Y	Y

Female is currently _____ Weeks pregnant OR ○ No longer Pregnant ○ Unknown

Female has elected to ○ Carry Pregnancy to Term
○ Terminate Pregnancy

Expected Date of Delivery:	D	D	M	O	N	Y	Y	Y	Y

Date Performed or Pending:	D	D	M	O	N	Y	Y	Y	Y

Reporters Information

Reporter's Name:	
Reporter's Contact Information/ Address:	
Reporter's Email Address:	

Date:	
Reporter's Signature:	
Reporter's Phone Number:	
Reporter's Fax Number:	

Patient's Prescribing Physician's Information:

Physician's Name:		Date:	
Physician's Contact Information/ Address:		Physician's Signature:	
Physician's Email Address:		Physician's Phone Number:	
		Physician's Fax Number:	

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Tel: +356 22294000, Email: eupvg@eugiapharma.com

Background Information on Reason for Pregnancy		
Was patient erroneously considered not to be of childbearing potential?	○ **Yes**	○ **No**
If yes, state reason for considering not to be of childbearing potential		
• Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year *amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential	○ **Yes**	○ **No**
• Premature ovarian failure confirmed by a specialist gynaecologist	○ **Yes**	○ **No**
• Previous bilateral salpingo-oophorectomy, or hysterectomy	○ **Yes**	○ **No**
• XY genotype, Turner syndrome, uterine agenesis.	○ **Yes**	○ **No**
Indicate from the list below what contraception was used		
• Implant	○ **Yes**	○ **No**
• Levonorgestrel-releasing intrauterine system (IUS)	○ **Yes**	○ **No**
• Medroxyprogesterone acetate depot	○ **Yes**	○ **No**
• Tubal sterilisation (specify below)	○ **Yes**	○ **No**
▪ Tubal ligation	○ **Yes**	○ **No**
▪ Tubal diathermy	○ **Yes**	○ **No**
▪ Tubal chips	○ **Yes**	○ **No**
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	○ **Yes** ○ **Yes**	○ **No** ○ **No**
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	○ **Yes**	○ **No**
• Other progesterone-only pills	○ **Yes**	○ **No**
• Combined oral contraceptive pill	○ **Yes**	○ **No**
• Other intra-uterine devices	○ **Yes**	○ **No**
• Condoms	○ **Yes**	○ **No**
• Cervical cap	○ **Yes**	○ **No**
• Sponge	○ **Yes**	○ **No**
• Withdrawal	○ **Yes**	○ **No**
• Other	○ **Yes**	○ **No**
• None	○ **Yes**	○ **No**
Indicate from the list below the reason for contraceptive failure		
• Missed oral contraception	○ **Yes**	○ **No**
• Other medication or intercurrent illness interacting with oral contraception	○ **Yes**	○ **No**

• Identified mishap with barrier method	○ **Yes**	○ **No**
• Unknown	○ **Yes**	○ **No**
• Had the patient committed to complete and continuous abstinence	○ **Yes**	○ **No**
• Was the drug started despite patient already being pregnant	○ **Yes**	○ **No**
• Did patient receive educational materials on the potential risk of teratogenicity	○ **Yes**	○ **No**
• Did patient receive instructions on need to avoid pregnancy	○ **Yes**	○ **No**

Lenalidomida Generis (lenalidomide)

Pregnancy Report Form

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This form must be returned to Eugia Pharma (Malta) Ltd.:

Tel: +356 22294000, Email: eupvg@eugiapharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Background Information on Reason for Pregnancy

Prenatal information

Date of Last Menstrual Period:	D	D	M	O	N	Y	Y	Y	Y

Estimated Delivery Date:	D	D	M	O	N	Y	Y	Y	Y

Pregnancy Test

Urine Qualitative ○	Reference Range:		Date:	D	D	M	O	N	Y	Y	Y

Serum Quantitative ○	Reference Range:		Date:	D	D	M	O	N	Y	Y	Y

Past Obstetric History

Year of Pregnancy	Outcome	Gestational Age	Type of Delivery
	□ Spontaneous abortion □Therapeutic abortion □Live birth □ Still birth		
	□ Spontaneous abortion □Therapeutic abortion □Live birth □ Still birth		
	□ Spontaneous abortion □Therapeutic abortion □Live birth □ Still birth		
	□ Spontaneous abortion □Therapeutic abortion □Live birth □ Still birth		
	□ Spontaneous abortion □Therapeutic abortion □Live birth □ Still birth		

Birth defects

Was there any birth defect from any pregnancy?	○ Yes	○ No	○Unknown
Is there any family history of any congenital abnormality abstinence?	○ Yes	○ No	○Unknown

If yes to either of these questions, please provide details below:

Maternal Past Medical History

Condition	Dates	Treatment	Outcome
	From: / To:		
	From:		

	To:										

	From:										
	To:										

	From:										
	To:										

	From:										
	To:										

Maternal Current Medical Conditions

Condition	From	Treatment

Maternal Social History

Alcohol ○ Yes ○ No
If yes, amount/units per day:

Tobacco ○ Yes ○ No
If yes, amount per day:

IV or recreational drug use ○ Yes ○ No
If yes, provide details:

Maternal medication during pregnancy and in 4 weeks before pregnancy

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Dates	Indication
	Start Date:	
	Stop Date/Continuing:	
	Start Date:	
	Stop Date/Continuing:	
	Start Date:	
	Stop Date/Continuing:	
	Start Date:	
	Stop Date/Continuing:	
	Start Date:	
	Stop Date/Continuing:	

	Start Date:										
	Stop Date/Continuing:										

Name of person completing this form

Name:	Signature:
Date:	

Lenalidomida Generis (lenalidomide)

Pregnancy Report Form

Pregnancy reports must be sent to Eugia Pharma (Malta) Ltd. IMMEDIATELY

This form must be returned to Eugia Pharma (Malta) Ltd.:

Tel: +356 22294000, Email: eupvg@eugiapharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Data Privacy Notice

Your personal data will be processed by Eugia Pharma (Malta) Ltd., as marketing authorisation holder of pharmaceutical products and its worldwide affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes.

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

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Under applicable law, you may have the right to access and verify your personal information held by Eugia Pharma (Malta) Ltd., receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing. If you wish to exercise those rights, you can contact our data protection officer at: dpo@aurobindo.com. You may also have the right to lodge a complaint with the supervisory authority enforcing data protection in your country. You can access the list of competent data protection authorities by visiting this URL: https://eur-lex.europa.eu/eli/reg/2016/679/oj.

Reporter's Signature (required):

Signature:

Date signed:	D	D	M	O	N	Y	Y	Y

On behalf of Eugia Pharma (Malta) Ltd. thank you for providing information that will assist us in our commitment to patient safety.

Lenalidomida Generis (lenalidomide)

Event-Specific Questionnaire for HCP – Pregnancy Outcome Form

This form must be returned to Eugia Pharma (Malta) Ltd.:

Tel: +356 22294000, Email: eupvg@eugiapharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Reporter information

Reporter Name:	
Address:	
City, County, Country:	
Phone No.:	
Fax No.:	

Patient information

Patient ID:		Date Of Birth	D	D	M	M	M	Y	Y	Y	Y

Ethnicity: ☐ White ☐ African-Caribbean ☐ Other, specify

Partner of patient information

☐ Not Applicable

Ethnicity: ☐ White ☐ African-Caribbean ☐ Other, specify

Partner of patient information

Date of Delivery:	D	D	M	M	M	Y	Y	Y	Y

Gestation age at delivery:	

Normal	☐ No ☐ Yes
C-section	☐ No ☐ Yes
Induced	☐ No ☐ Yes
Ectopic pregnancy	☐ No ☐ Yes

Elective termination ☐ No ☐ Yes

Spontaneous abortion (≤20 weeks) ☐ No ☐ Yes

Foetal death/stillbirth (≥20 weeks) ☐ No ☐ Yes

Were the products of conception examined? ☐ No ☐ Yes

If yes, was the foetus normal? ☐ No ☐ Yes ☐ Unknown If no, Describe Below:

Obstetrics information

Complications during pregnancy ☐ No ☐ Yes

If yes, please specify

Complications during labour/delivery ☐ No ☐ Yes

If yes, please specify

Post-partum maternal complications ☐ No ☐ Yes

If yes, please specify

Foetal outcome

Live normal infant ☐ No ☐ Yes

Foetal distress ☐ No ☐ Yes

Intra-uterine growth retardation ☐ No ☐ Yes

Neonatal complication ☐ No ☐ Yes if yes, Please specify

Elective termination ☐ No ☐ Yes if yes, Please specify

Sex: ☐ Male ☐ Female **Birth weight** _____lbs____oz. or _____kg **Length**:_____Inches Or ____cm.

Apgar score: 1 min: ____ 5 min: ____ 10 min: ____ ☐ Unknown

Signature of person completing this form

Signature:	Date	D	D	M	M	M	Y	Y	Y	Y

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Reporter's Signature (required):

Signature:	Date	D	D	M	M	M	Y	Y	Y	Y

On behalf of Eugia Pharma (Malta) Ltd., thank you for providing information that will assist us in our commitment to patient safety.

Lenalidomida Generis (lenalidomide)

Adverse Event Form

This form must be returned to Eugia Pharma (Malta) Ltd.:

Tel: +356 22294000, Email: eupvg@eugiapharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:	

☐New ☐ Follow-Up

For Studies Enter	
Protocol:	
Site Number:	
Patient number:	

For xxxxx use only			
Date of receipt:	DD	MMM	YYYY
Received by: (Name and organisation – eg CRO, or company representative)			

Source:☐	Spontaneous :☐	Comp. Use☐	Lit. ☐	Other, Specify:

Suspect Drug

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

Action Taken

☐ None ☐ Unknown ☐ Not Applicable

☐ Dose decreased, specify ☐ Permanently discontinued

☐ Dose increased, specify ☐ Temporarily interrupted

Patient Data

Initials:			DOB:	DD	MMM	YYYY	Age:	

Weight:	kg	Height:	cm	Gender:	☐ Male ☐ Female

Lenalidomida Generis (lenalidomide)

Adverse Event Form

This form must be returned to Eugia Pharma (Malta) Ltd.:

Tel: +356 22294000, Email: eupvg@eugiapharma.com

NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:	

Adverse Event

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

Event onset date:	DD	MMM	YYYY
Event stop date:	DD	MMM	YYYY

Adverse Event

☐ Recovered

☐ Recovered with sequelae

☐ Not recovered

☐ Unknown

☐ Death

Date of death:	DD	MMM	YYYY

Did the event result in hospitalisation or prolonged hospitalisation? ☐ Yes ☐ No

Cause(s) of death:

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

Medical History

☐ Yes (if yes, please specify)

☐ None

☐ Unknown

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

Lenalidomida Generis (lenalidomide)

Adverse Event Form

Drug, Dosage-form, Strength, Route (eg. Tab 5mg, oral)	Dose & frequency	Therapy start date: DD/MON /YYYY	Therapy stop date: DD/MON /YYYY	Indication for use of drug
		/ / /	/ / /	
		/ / /	/ / /	
		/ / /	/ / /	
		/ / /	/ / /	
		/ / /	/ / /	
		/ / /	/ / /	
		/ / /	/ / /	
		/ / /	/ / /	
Has the patient discussed this event with their healthcare professional?		☐ Yes (If yes, would you please provide their healthcare professional's contact information below?) ☐ No ☐Unknown		

Healthcare professional's contact information

Name:		Fax:	
Address:		Phone:	
		Email:	
Country:			

Reporter

☐ Physician ☐ Nurse ☐ Pharmacist ☐ Patient ☐ Relative ☐ Other, Please specify

Name:		Fax:	
Address:		Phone:	
		Email:	
Country:			

Pharmacy Name (if applicable)

Name:		Email:	

Signature

Sign:		Date of AE awareness:	DD	MMM	YYYY

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This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP

Please chose one, as applicable:

☐ I grant Eugia Pharma (Malta) Ltd. permission to contact the prescriber/physician/HCP who treated me/the affected patient when the side effect(s) occurred and authorise him/her to provide data from my medical record related to the event(s) occurred.

☐ No, I do not grant Eugia Pharma (Malta) Ltd. permission to contact the prescriber/physician/HCP who treated me/the patient.

If you grant Eugia Pharma (Malta) Ltd. permission, please provide the information of the prescriber/physician/HCP.

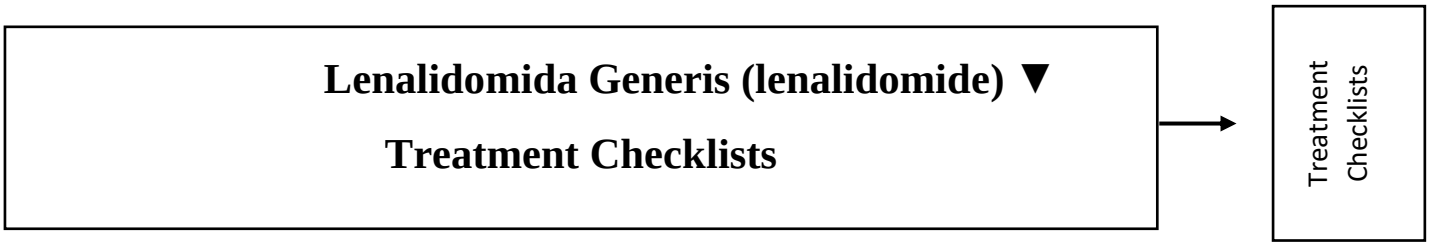
Lenalidomida Generis (lenalidomide)

Adverse Event Form

Contact information

Name:		Fax:	

Address:		Phone:	
		Email:	
Country:			


Lenalidomida Generis (lenalidomide) ▼
Treatment Checklists
Treatment Checklists

COMBINED CHECKLIST FOR COMMENCING LENALIDOMIDA GENERIS (LENALIDOMIDE) ▼ TREATMENT

This checklist is to assist you with counselling a patient before they commence Lenalidomida Generis (lenalidomide) treatment in order to assure it is used safely and correctly. Please choose the applicable column for the risk category of the patient and refer to the counselling messages provided.

Counselling	Women of Child Bearing Potential	Women of Non-Child Bearing Potential*	Male
Inform of expected Teratogenic risk to the unborn child	●	●	●
Inform of the need for effective contraception** for at least 4 weeks before starting treatment, throughout the entire duration of treatment, including during treatment interruptions, and for at least 4 weeks after the end of treatment, or absolute and continued abstinence	●		
Inform that even if patient has amenorrhoea they must comply with advice on contraception	●		
Confirm if patient is capable of complying with contraceptive measures	●		●
Inform of the expected consequences of pregnancy and the need to consult rapidly if there is a risk of pregnancy	●		●
Inform the need to stop treatment immediately if female patient is suspected to the pregnant	●		
Confirm patient agrees to undergo pregnancy testing at least in 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, during treatment interruptions and for at least 7 days following discontinuation	●	●	●
Inform of the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain Lenalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential 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 she 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 prescriber immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice			●

* Refer to Healthcare Professional brochure for criteria to determine if patient is a woman of non-childbearing potential.
**Refer to Healthcare Professional brochure for information on contraception

Contraceptive referral	Women of Child Bearing Potential	Women of Non-Child Bearing Potential*	Male
Contraceptive referral required	●		
Contraceptive referral made	●		
Contraceptive consultation completed	●		

Contraception Patient is currently established on one of the following for at least 4 weeks	Women of Child Bearing Potential	Women of Non-Child Bearing Potential*	Male
Implant	●		
Levonorgestrel-releasing intrauterine System (IUS)	●		
Medroxyprogesterone acetate depot	●		
Sterilization	●		
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analysis	●		
Ovulation inhibitory progesterone-only pills (i.e desogesterol)	●		
Patient commits to complete and absolute abstinence	●		
Negative pregnancy test before starting treatment	●		

Not of Childbearing Potential One of the following Criteria have been met to determine patient is women NCBP	Women of Child Bearing Potential	Women of Non-Child Bearing Potential*	Male
Age≥50 years and naturally amenorrhoeic***for ≥1 year not included by chemotherapy		●	
Premature ovarian failure confirmed by specialist gynaecologist		●	
Bilateral Salpingo-oophorectomy		●	
XY genotype, Turner syndrome, uterine agensis		●	

***Amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential.

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE

Eugia Pharma (Malta) Ltd.

Vault 14, Level 2, Valletta Waterfront, Floriana, FRN 1914, Malta

Distributed by Cherubino Limited - DELF Building, Sliema Road, Gzira, GZR 1637, Malta

Date of preparation of text:

October 27th, 2023

Approved by Malta Medicines Authority: January 29th, 2024

These documents can also be found at https://medicinesauthority.gov.mt/rmm