Amarox

Lenamid (Lenalidomide) 5mg , 10mg, 25mg Capsules

Healthcare Professional Information Pack

Important Safety Information for Healthcare Professionals

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Version.2

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Introduction

Lenalidomide belongs to the class of immunomodulatory drugs known as IMiDs compounds.

IMiDs compounds are structurally related to Thalidomide, i.e. compounds that have been designed using the Thalidomide structural backbone but with chemical modifications to optimize their immunological and anticancer properties.

Lenalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Lenalidomide induced, in rats and rabbits, malformations similar to those described with thalidomide.

If Lenalidomide is taken during pregnancy, a teratogenic effect in humans is expected. Lenalidomide is therefore contraindicated in pregnant women and in Females of Child Bearing Potential (FCBP) unless they adhere to the conditions of the Lenalidomide Pregnancy Prevention Program.

The conditions of the Lenalidomide Pregnancy Prevention Program must be fulfilled for all male and female patients.

Lenalidomide will only be available under a special distribution program. The aims of this program are to:

• Ensure that use and distribution of Lenalidomide are closely monitored and well controlled

a. Only prescribers registered with program can prescribe Lenalidomide

b. Patients must enroll in the program to receive Lenalidomide

c. Only pharmacists/pharmacies registered with program can dispense Lenalidomide

• Ensure that patients taking Lenalidomide are fully informed about their treatment and –most importantly – that they take all necessary steps to avoid exposing unborn babies to Lenalidomide

a. Prescribers must inform patients about the likely benefits and potential risks of Lenalidomide therapy, and properly explain how potential risks can be avoided or minimized

b. Patients must formally agree to fully comply with the requirements of the program, by signing a "Lenalidomide Treatment Initiation Form"

c. Females of Child bearing Potential (FCBP) are mandated to perform pregnancy tests before taking Lenalidomide and later on with every single dispense (every 4 weeks), including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation.

d. Prescribers must provide patients a "Lenalidomide patient brochure"

Responsibilities for registered participants

Prescribers:

1. All prescribers MUST be registered with Program to prescribe Lenalidomide
   a. To register, prescribers must complete a "Lenalidomide Prescriber Registration Form" after receiving this "Lenalidomide Healthcare Professional Information Pack"
   b. Complete and sign the "Lenalidomide Prescriber Registration Form" and provide.
   c. For further information about the registration process please contact your local medical representative.

2. Prescriber MUST agree to the following:
    a) Provide counseling to each patient:
        - Why it is important not to expose unborn babies to Lenalidomide and what patients can do to prevent such exposure
        - What registered patients responsibilities are in this regard
        - Advise all patients on Lenalidomide not to donate blood
        - Advise all male patients not to donate semen or sperm when taking
        - Lenalidomide advise all patients who are or might be engaged in any sexual activity to adhere to the effective contraception methods
        - Advise all FCBP patients not to breast feed if Lenalidomide therapy was initiated post-partum
        - Advise all patients not to share Lenalidomide
        - Return unused Lenalidomide to the pharmacist
        - On the likely benefits and possible side effects of Lenalidomide treatment
            - How to recognize potentially serious side effects
            - How to minimize the risk of developing serious side effects
            - What to do if symptoms of potentially serious side effects develop

    b) Prescribe no more than a 4-week (28 day) supply of Lenalidomide per prescription for females of childbearing potential, or a maximum of 12-week (84-day) supply for all other patients
    c) Provide each patient with the "Lenalidomide Patient Brochure "
    d) Enroll each patient by submitting a completed and signed "Lenalidomide Treatment Initiation Form" for each new patient being prescribed Lenalidomide. This form must be completed by both the prescriber and the patient. The "Lenalidomide Treatment Initiation Form" is a written confirmation that the patient has received and understood information on the safe use of Lenalidomide. This form is to be completed at initiation of treatment for the first time or after there has been a change in the patient's risk category (e.g. Female of childbearing potential changes to female not of childbearing potential).
    e) Send the "Lenalidomide Treatment Initiation Form" e.g. by email.
    f) Retain a copy of the "Lenalidomide Treatment Initiation Form" in the patient's file
    g) Then register the patient and forward a "Patient Registration Confirmation Letter" with a "Unique Patient Identification Number" (UPIN) to the prescriber. The UPIN must be written on each new "Lenalidomide Prescription Authorization Form", which must accompany each prescription for that particular patient. The "Lenalidomide Prescription Authorization Form" shows:
        • Patient was counseled on safe use of Lenalidomide
        • Patient risk category (female of childbearing potential; female NOT of childbearing potential; male)
        •Pregnancy test date and result for female of childbearing potential (Prescriptions must be dispensed within a maximum of 7 days after the last negative pregnancy test date)
        • Dosing prescribed
        • Milligram strength and number of capsules to be dispensed
    h) Provide the patient with a completed and signed "Lenalidomide Prescription Authorization Form" with each Lenalidomide prescription. The patient must present

this form to the pharmacy, along with his prescription, or the prescriber may send the "Lenalidomide Prescription Authorization Form" with each prescription prescription to the pharmacy

i) Adhere to guidelines when writing a prescription for Lenalidomide

Patients:

a. Patients must be enrolled in the program to receive Lenalidomide

1. Each patient (or his/her parent, legal guardian or authorized representative) must complete and sign the "Lenalidomide Treatment Initiation Form"
2. Patients must present the "Lenalidomide Prescription Authorization Form" to the pharmacy, along with their prescription or the prescriber may send the "Lenalidomide Prescription Authorization Form" and the Lenalidomide prescription to the pharmacy

b. Patients must agree to comply with all requirements of the program

1. Each patient must take all necessary steps to avoid exposing an unborn baby to Lenalidomide

Pharmacists:

a. Pharmacies must be registered with Program in order to dispense Lenalidomide

1. To register, pharmacies must complete and sign a "Lenalidomide Pharmacy Registration Form" after receiving this "Lenalidomide Healthcare Professional Information Pack" and send the completed form to Biologix

2. Biologix will approve dispenses and authorize shipments to the registered pharmacy

3. For further information about the registration process please contact Tel XXXX or your local medical representative

b. Registered pharmacists MUST agree to do the following:

1. Obtain a Lenalidomide prescription and the "Lenalidomide Prescription Authorization Form" and check the "Lenalidomide Prescription Authorization form" for completeness.
2. Provide counseling to each patient and fill the "Education and Counseling Check list used by the Registered Pharmacy".
3. Send the signed "Lenalidomide Prescription Authorization Form" and "Education and Counseling Check list" e.g. by email.
4. Dispense to a patient Lenalidomide as per approval sent by fax to the pharmacy
5. Dispense no more than a 4-week (28-day) supply of Lenalidomide for FCBP and up to a maximum of 12-week (84-day) supply for all other patient risk categories provided it was so approved.
6. A new prescription is required for further dispensing.
7. For subsequent prescriptions, verify there are 7 days or less since the last pregnancy test occurred.
8. For subsequent prescriptions, verify there are 7 days or less remaining of the 28-day cycles on the existing prescription.

What registered prescribers must do before prescribing Lenalidomide according to patient risk categories

The Program segments Lenalidomide patients in different risk categories according to their childbearing potential

1. Female of childbearing potential
    - Females who do not meet the below definition of Female NOT of childbearing potential should be classified as FCBP.
2. Female NOT of childbearing potential
    - Females 50 years old and naturally amenorrhoeic for 2 years
        - Amenorrhoea following cancer therapy or during breast-feeding does not does not rule out childbearing potential
    - Females that have premature ovarian failure confirmed by a gynecologist
    - Females that have not begun menstruation
    - Females with bilateral salpingo-oophorectomy or hysterectomy
    - Females with XY genotype, Turner's syndrome or uterine agenesis
3. Male
    - To minimize the risk of a pregnancy occurring under the treatment of Lenalidomide there are different requirements for each of these patient's risk categories.

Requirements for females of childbearing potential (FCBP)

- **Pregnancy testing**
  To confirm absence of a pregnancy, FCBP must have a medically supervised negative pregnancy test with a minimum sensitivity of 50 mIU/ml before starting Lenalidomide.
    - A medically supervised pregnancy test should be performed during the consultation, when Lenalidomide is prescribed, or in the 7 days prior to the visit to the prescriber once the patient had been using effective contraception for at least 4 weeks. The test should ensure that the FCBP patient is not pregnant when she starts treatment with Lenalidomide.
    - During treatment, a medically supervised pregnancy test should be repeated every 4 weeks, including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation.
    - The prescriber documents the date and result of each pregnancy test on the "Lenalidomide Prescription Authorization Form".

1. Contraception requirements for females of childbearing potential
    - MUST be established on effective contraception for at least 4 weeks before initiating Lenalidomide therapy
    - Use simultaneously two reliable methods of contraception simultaneously for 4 weeks before Lenalidomide therapy, during therapy, during dose interruption and until 4 weeks after therapy

    There must be no more than 7 days between the dates of the last negative pregnancy test and the dispensing of Lenalidomide. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day if not established on effective contraception, the patient should be referred to an appropriately trained Healthcare Professional for contraceptive advice before initiating Lenalidomide treatment.

2. Examples of effective methods of contraception
    a) Highly effective methods
        - Intra Uterine Device (IUD)
        - Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
        - Tubal ligation
        - Partner's vasectomy
    b) Effective methods
        - Male condom
        - Diaphragm
        - Cervical cap

Contraceptive methods must include: At least 1 highly effective method AND 1 additional effective barrier method used at the same time.

Hormonal contraception should be initiated 4 weeks before starting Lenalidomide treatment.

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking Lenalidomide and dexamethasone, combined oral contraceptive pills are not recommended.

Advise patient that if a pregnancy does occur whilst she is receiving Lenalidomide, she must stop treatment immediately and inform her doctor immediately.

3. In the event of pregnancy whilst on treatment with Lenalidomide
    - Stop treatment with Lenalidomide
    - Refer the patient to a Gynecologist/Obstetrician experienced in reproductive toxicity

Requirements for females not of childbearing potential

- Provide counseling as described in above section (Prescribers)
- Treating Physicians are advised to refer their patient for a gynecological opinion if at all unsure as to whether a woman meets the criteria for being of a female NOT of childbearing potential.

Requirements for males

Traces of Lenalidomide are present in semen, therefore:

- Male patients should practice complete abstinence or use condoms during sexual intercourse with a pregnant female or a female of childbearing potential throughout the duration of treatment, during dose interruption and for 4 weeks after cessation of treatment if their partner is not established on suitable contraception (even if the male patient has undergone vasectomy)
- Male patients must not donate semen or sperm during therapy including dose interruptions and for 4 weeks following the discontinuation of Lenalidomide

Male patients should be instructed that if their partner becomes pregnant whilst they take Lenalidomide or shortly after the patient stopped Lenalidomide treatment, he should inform his doctor immediately. Inform your patient which are the effective contraceptive methods that his female partner can use.

4. Writing subsequent Lenalidomide prescriptions

When a patient requires a new prescription, simply record the UPIN on the "Lenalidomide Prescription Authorization Form" which should accompany the Lenalidomide prescription

5. Reporting of Adverse Events

The safe use of Lenalidomide is of paramount importance. As part of the ongoing safety monitoring, wish to learn of Adverse Events that have occurred during the use of Lenalidomide

6. For ADR reporting

Adverse Reaction report forms are included in this Healthcare Professional Pack and should be forwarded to Saudi Amarox at the address below. They should also be reported to the SFDA using the following:

The National Pharmacovigilance Centre
Saudi Food and Drug Authority
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

Saudi Amarox contact details:
Razan Almalki- Qualified Person for Pharmacovigilance
Al Jamiyah Street, Al Malaz - Riyadh code 12629, Saudi Arabia
E-mail: PVsaudi@Amaroxpharma.com
Phone: +966 11 226 8850
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