



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

Patient Brochure

Important Risk Minimization Information for Patients

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

Introduction

Your Doctor intends to prescribe Lenalidomide for you.

Lenalidomide (the trade name for lenalidomide) is a structural analogue to Thalidomide.

Thalidomide is a known teratogen that causes severe life-threatening human birth defects. If Lenalidomide is taken during pregnancy it may cause birth defects or death to an unborn baby.

To avoid fetal exposure, Lenalidomide is available only under a special distribution program.

The program is designed to ensure that Lenalidomide therapy is always prescribed and taken in the recommended way.

Key features of the program:

- Only physicians registered with program can prescribe Lenalidomide
- Only pharmacists/pharmacies registered with program can dispense Lenalidomide
- Only patients who have been formally enrolled in the program can receive Lenalidomide

To enroll, patients must sign a “Lenalidomide Treatment Initiation Form” and agree to fully comply with all requirements of the program.

Important to remember:

Lenalidomide may cause birth defects or death to unborn babies.

Special Requirements for Females who are Able to Become Pregnant

Include:

- Females younger than 50 years
- Females that are not naturally postmenopausal for at least two years
- Females that have not had a hysterectomy

Important: do NOT become pregnant:

- During the four weeks before starting Lenalidomide treatment
- While taking Lenalidomide
- During any interruption in Lenalidomide treatment
- During the four-week period following the conclusion of your Lenalidomide treatment

Before starting treatment:

1. You must sign a Lenalidomide Treatment Initiation Form”, agreeing not to become pregnant while taking Lenalidomide and following all requirements within program.
2. You must use two reliable methods of birth control (contraception) at the same time 4 weeks before starting Lenalidomide treatment. Refer below for examples of suitable methods of contraception:
 - 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
- Effective methods
 - ✓ Male condom
 - ✓ Diaphragm
 - ✓ Cervical cap

Contraceptive methods must include:

1. At least 1 highly effective method AND 1 additional effective barrier method used at the same time.
2. You must have a medically supervised pregnancy test done during your consultation with the doctor, when Lenalidomide is prescribed, or in the 3 days prior to the visit to the doctor once you had been using effective contraception for at least 4 weeks. The test should ensure that you are not pregnant when you start treatment with Lenalidomide
3. You must agree to not breastfeed or donate blood
4. You must agree to never share your Lenalidomide capsules
5. You must agree to return unused Lenalidomide capsules to your pharmacist

During treatment and dose interruptions:

1. You must continue to use two reliable methods of birth control (contraception) at the same time during treatment and during any interruption in Lenalidomide treatment
2. You must also undergo regular medically supervised pregnancy tests every four weeks during treatment
3. You must not breastfeed or donate blood
4. Never share your Lenalidomide capsules

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- ✓ Stop Lenalidomide immediately
- ✓ Tell your doctor
- ✓ Have a pregnancy test

For four weeks after treatment:

1. You must continue to use two reliable methods of birth control (contraception) at the same time
2. You must not breastfeed or donate blood
3. Never share your Lenalidomide capsules
4. Return unused Lenalidomide capsules to your pharmacist
5. You must undergo a medically supervised pregnancy test 4 weeks after discontinuation of Lenalidomide therapy

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Tell your doctor
- Have a pregnancy test

Requirements for Females who are NOT Able to Become Pregnant Include:

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as Females of childbearing potential (FCBP).

- Females ≥ 50 years old and naturally amenorrheic for ≥ 2 years
 - Amenorrhea following cancer therapy does not rule out childbearing potential
- Females that have premature ovarian failure confirmed by a gynaecologist
- Females with bilateral salpingo-oophorectomy or hysterectomy
- Females with XY genotype, Turner's syndrome or uterine agenesis

Before starting treatment:

1. You must sign a "Lenalidomide Treatment Initiation Form", indicating that you are not pregnant and do not have the ability to have children and will follow all requirements within.
2. You must agree to not donate blood
3. You must agree to never share your Lenalidomide capsules
4. You must agree to return unused Lenalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1. You must not donate blood
2. Never share your Lenalidomide capsules

For four weeks after treatment:

1. You must not donate blood
2. Return unused Lenalidomide capsules to your pharmacist

Requirements for Male Patients

Before starting treatment:

Lenalidomide is present in semen. You must sign a Lenalidomide Treatment Initiation Form”, agreeing to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) and will follow all following requirements within including the following:

- You must agree to not donate blood, sperm or semen
- You must agree to never share your Lenalidomide capsules
- You must agree to return unused Lenalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1. You must use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)
2. You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant
3. You must not donate blood, sperm or semen
4. Never share your Lenalidomide capsules

For four weeks after treatment:

1. You must continue to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)
2. You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant
3. You must not donate blood, sperm or semen
4. Never share your Lenalidomide capsules
5. Return unused Lenalidomide capsules to your pharmacist

Special Warnings and Precautions

Low white blood cells (neutropenia) and low platelets (thrombocytopenia).

Lenalidomide causes low white blood cells and low platelets in most patients. You may need a blood transfusion or certain medicines if your blood counts drop too low. If you are being treated for del 5q myelodysplastic syndromes (MDS) your blood counts should be checked weekly during the first 8 weeks of treatment with Lenalidomide, and at least monthly thereafter. If you are being treated for multiple myeloma, your blood counts should be checked every 2 weeks for the first 12 weeks and then at least monthly thereafter.

A higher chance for blood clots in your veins and lungs.

Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:

- a. shortness of breath
- b. chest pain

c. arm or leg swelling

Possible side effects of Lenalidomide

Lenalidomide may cause serious side effects.

Serious skin reactions: Serious skin reactions can happen with Lenalidomide and may cause death. Call your healthcare provider right away if you have any skin reaction while taking Lenalidomide.

Tumor lysis syndrome: Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the breakdown products of dying cancer cells and may include the following: changes to blood chemistry, high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

Common side effects of Lenalidomide are:

diarrhea

itching

rash

tiredness

These are not all the possible side effects of Lenalidomide. Tell your healthcare provider about any side effect that bothers you or that does not go away.

How should you take Lenalidomide?

Take Lenalidomide exactly as prescribed and follow all the instructions of the program.

Swallow Lenalidomide capsules whole with water once a day. Do not break, chew, or open your capsules.

Do not open the Lenalidomide capsules or handle them any more than needed. If you touch a broken Lenalidomide capsule or the medicine in the capsule, wash the area of your body with soap and water.

If you miss a dose of Lenalidomide, and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do not take 2 doses at the same time.

If you take too much Lenalidomide or overdose, call your healthcare provider or poison control center right away.

Want to Know More?

For more information about Lenalidomide, speak with your doctor or call SFDA.

The National Pharmacovigilance Centre Saudi Food and Drug Authority	Saudi AmaroX contact details:
Call Center: 19999 E-mail: npc.drug@sFDA.gov.sa Website: https://ade.sFDA.gov.sa/	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 Mobile: +966531215235