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## Lenalidomide

pronounced as (len a lid' oh mide)

### IMPORTANT WARNING:

Risk of severe life-threatening birth defects caused by lenalidomide:

*For all patients:*

Lenalidomide must not be taken by patients who are pregnant or who may become pregnant. There is a high risk that lenalidomide will cause severe birth defects (problems that are present at birth) or death of the unborn baby.

A program called REVLIMID REMS™ has been set up to make sure that pregnant women do not take lenalidomide and that women do not become pregnant while taking lenalidomide. All patients, including women who cannot become pregnant and men, can get lenalidomide only if they are registered with REVLIMID REMS, have a prescription from a doctor who is registered with REVLIMID REMS, and fill the prescription at a pharmacy that is registered with REVLIMID REMS.

You will receive information about the risks of taking lenalidomide and must sign an informed consent sheet stating that you understand this information before you can receive the medication. If you are younger than 18 years of age, a parent or guardian must sign the consent sheet and agree to make sure you meet these requirements. You will need to see your doctor during your treatment to talk about your condition and the side effects you are experiencing or to have pregnancy tests as recommended by the program. You may need to complete a confidential survey at the beginning of your treatment and at certain times during your treatment to be sure that you have received and understand this information and that you can follow the instructions to prevent serious risks to unborn babies.

Tell your doctor if you do not understand everything you were told about lenalidomide and the REVLIMID REMS program and how to use the birth control methods discussed with your doctor, or if you do not think you will be able to keep appointments.

Do not donate blood while you are taking lenalidomide, during any breaks in your treatment, and for 4 weeks after your final dose.

Do not share lenalidomide with anyone else, even someone who has the same symptoms that you have.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with lenalidomide and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs> [http://www.fda.gov/Drugs] ), the manufacturer's website, or the REVLIMID REMS program website (<http://www.revlimidrems.com> [http://www.revlimidrems.com] ) to obtain the Medication Guide.

Talk to your doctor about the risks of taking lenalidomide.

*For female patients:*

If you can become pregnant, you will need to meet certain requirements during your treatment with lenalidomide. You must use two acceptable forms of birth control for 4 weeks before you begin taking lenalidomide, during your treatment, including at times when your doctor tells you to temporarily stop taking lenalidomide, and for 4 weeks after your final dose. Your doctor will tell you which forms of birth control are acceptable and will give you written information about birth control. You must use these two forms of birth control at all times unless you can guarantee that you will not have any sexual contact with a male for 4 weeks before your treatment, during your treatment, during any interruptions in your treatment, and for 4 weeks after your final dose.

If you choose to take lenalidomide, it is your responsibility to avoid pregnancy for 4 weeks before, during, and for 4 weeks after your final dose. You must understand that any form of birth control can fail. Therefore, it is very important to decrease the risk of accidental pregnancy by using two forms of birth control. Tell your doctor if you do not understand everything you were told about birth control or you do not think that you will be able to use two forms of birth control at all times.

You must have two negative pregnancy tests before you can begin to take lenalidomide. You will also need to be tested for pregnancy in a laboratory at certain times during your treatment. Your doctor will tell you when and where to have these tests.

Stop taking lenalidomide and call your doctor right away if you think you are pregnant, you miss a menstrual period, you have unusual menstrual bleeding, or you have sex without using two forms of birth control. If you become pregnant during your treatment or within 30 days after your treatment, your doctor will contact the REVLIMID REMS program, the manufacturer of lenalidomide, and the Food and Drug Administration (FDA). You will also talk with a doctor who specializes in problems during pregnancy who can help you make choices that are best for you and your baby. Information about your health and your baby's health will be used to help doctors learn more about the effects of lenalidomide on unborn babies.

*For male patients:*

Lenalidomide is present in your semen when you take this medication. You must always use a latex condom, even if you have had a vasectomy (surgery that prevents a man from causing a pregnancy), every time you have sexual contact with a female who is pregnant or able to become

pregnant while you are taking lenalidomide, during any breaks in your treatment, and for 4 weeks after your final dose. Tell your doctor if you have sexual contact with a female without using a condom or if your partner thinks she may be pregnant during your treatment with lenalidomide.

Do not donate sperm while you are taking lenalidomide, during any breaks in your treatment, and for 4 weeks after your final dose.

Other risks of taking lenalidomide:

Lenalidomide may cause a decrease in the number of certain types of blood cells in your body. Your doctor will order laboratory tests regularly during your treatment to see how much the number of blood cells has decreased. Your doctor may decrease your dose, interrupt your treatment, or treat you with other medications or treatments if the decrease in your blood cells is severe. If you experience any of the following symptoms, tell your doctor immediately: sore throat, fever, chills, and other signs of infection; easy bruising or bleeding; bleeding gums; or nosebleeds.

If you are taking lenalidomide with dexamethasone to treat multiple myeloma, there is an increased risk that you will develop a blood clot in your leg that may move through the bloodstream to your lungs, or have a heart attack or a stroke. Your doctor may prescribe other medication to be taken along with lenalidomide to decrease this risk. Tell your doctor if you smoke, if you have ever had a serious blood clot, and if you have or have ever had high blood pressure or a high level of fat in your blood. Also tell your doctor about all the medications you are taking because certain medications may increase the risk that you will develop a blood clot while taking lenalidomide with dexamethasone including darbepoetin (Aranesp), epoetin alfa (Epogen, Procrit), and medications containing estrogen such as hormone replacement therapy or hormonal contraceptives (birth control pills, patches, rings, implants, or injections). If you experience any of the following symptoms, tell your doctor immediately: shortness of breath; chest pain that may spread to the arms, neck, back, jaw, or stomach; cough; redness or swelling in an arm or leg; sweating; nausea; vomiting; sudden weakness or numbness, especially on one side of the body; headache; confusion; or difficulty with vision, speech, or balance.

## Why is this medication prescribed?

Lenalidomide is used to treat a certain type of myelodysplastic syndrome (a group of conditions in which the bone marrow produces blood cells that are misshapen and does not produce enough healthy blood cells). Lenalidomide is also used along with dexamethasone to treat people with multiple myeloma (a type of cancer of the bone marrow). It is also used to treat people with multiple myeloma after a hematopoietic stem-cell transplant (HSCT; procedure in which certain blood cells are removed from the body and then returned to the body). Lenalidomide is also used to treat people with mantle cell lymphoma (a fast-growing cancer that begins in the cells of the immune system) who have been treated with bortezomib (Velcade) and at least one other medication. Lenalidomide should not be used to treat people with chronic lymphocytic leukemia (a type of cancer of the white blood cells that gets worse slowly over time) unless they are participating in a clinical trial (research study to see whether a medication may be used safely and effectively to treat a certain condition). Lenalidomide is in a class of medications

called immunomodulatory agents. It works by helping the bone marrow to produce normal blood cells and by killing abnormal cells in the bone marrow.

## How should this medicine be used?

Lenalidomide comes as a capsule to take by mouth. When lenalidomide is used to treat myelodysplastic syndrome, it is usually taken with or without food once daily. When lenalidomide is used to treat multiple myeloma or mantle cell lymphoma, it is usually taken with or without food once daily for the first 21 days of a 28-day cycle. When lenalidomide is used to treat multiple myeloma after HSCT, it is usually taken with or without food once daily for 28 days of a 28-day cycle. The 28-day cycle regimen may be repeated as recommended by your doctor based on your body's response to this medication. Take lenalidomide at around the same time of day every day that you take it. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take lenalidomide exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with plenty of water; do not break, chew, or open them. Handle the capsules as little as possible. If you touch a broken lenalidomide capsule or the medicine in the capsule, wash that area of your body with soap and water. If the medicine in the capsule gets into your mouth, nose, or eyes, wash it away with plenty of water.

Your doctor may need to interrupt your treatment or reduce your dose if you experience certain side effects. Be sure to tell your doctor how you are feeling during your treatment with lenalidomide.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking lenalidomide,

- tell your doctor and pharmacist if you are allergic to lenalidomide, any other medications, or any of the ingredients in lenalidomide capsules. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and digoxin (Lanoxin). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you are lactose intolerant and if you have or have ever had kidney, thyroid, or liver disease. Also tell your doctor if you have ever taken thalidomide (Thalomid) and developed a rash during your treatment.
- tell your doctor if you are breastfeeding or are planning to breastfeed.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

If it has been less than 12 hours since you were scheduled to take the dose, take the missed dose as soon as you remember it. If it has been more than 12 hours, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Lenalidomide may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- diarrhea
- constipation
- stomach pain
- loss of appetite
- weight loss
- weakness
- dizziness
- change in ability to taste
- pain or burning of the tongue, mouth, or throat
- decreased sense of touch
- burning or tingling in the hands or feet
- difficulty falling asleep or staying asleep
- depression
- joint, muscle, bone, or back pain
- painful, frequent, or urgent urination
- sweating
- dry skin
- abnormal hair growth in women
- uncontrollable shaking of a part of the body
- decrease in sexual desire or ability

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency medical treatment:**

- swelling of the face, throat, tongue, lips, eyes, arms, hands, feet, ankles, or lower legs
- difficulty breathing or swallowing
- hoarseness

- fast, slow, pounding, or irregular heartbeat
- seizures
- rash
- skin pain
- blistering, peeling, or shedding skin
- swollen glands in the neck
- muscle cramps
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- dark colored urine
- tiredness
- bloody, cloudy, or painful urination
- increased or decreased urination

If you are taking lenalidomide to treat multiple myeloma and you also receive melphalan (Alkeran) or a blood stem cell transplant, you may have a higher risk of developing new cancers. Talk to your doctor about the risks of taking lenalidomide. Your doctor will check you for new cancers during your treatment with lenalidomide.

Lenalidomide may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Return any medication that is outdated or no longer needed to your doctor, the pharmacy that gave you the medication, or the manufacturer.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## **In case of emergency/overdose**

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## **Symptoms of overdose may include the following:**

- itching
- hives
- rash

## What other information should I know?

Keep all appointments with your doctor. Your doctor may order certain tests before and during your treatment to check your body's response to lenalidomide.

Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Revlimid®

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