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MEDICATION GUIDE

Lenalidomide (leh-nah-LIH-doe-mide)
Capsules
Rx only

What is the most important information I should know about lenalidomide capsules?

Before you begin taking lenalidomide capsules, you must read and agree to all of the instructions in the Lenalidomide REMS program. Before prescribing lenalidomide capsules, your healthcare provider will explain the Lenalidomide REMS program to you and have you sign the Patient-Physician Agreement Form.

Lenalidomide capsules may cause serious side effects including:

- **Possible birth defects (deformed babies) or death of an unborn baby.** Females who are pregnant or who plan to become pregnant must not take lenalidomide capsules.

  Lenalidomide capsules are similar to the medicine thalidomide. We know thalidomide can cause severe life- threatening birth defects. Lenalidomide capsules have not been tested in pregnant females. Lenalidomide capsules have harmed unborn animals in animal testing.

  Females must not get pregnant:
  - For at least 4 weeks before starting lenalidomide capsules
  - While taking lenalidomide capsules
  - During any breaks (interruptions) in your treatment with lenalidomide capsules
  - For at least 4 weeks after stopping lenalidomide capsules

  Females who can become pregnant:
  - Will have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual cycle is regular, or every 2 weeks if your menstrual cycle is irregular.
  - If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.
  - Must agree to use two acceptable forms of birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in your treatment, and for at least 4 weeks after stopping lenalidomide capsules.
  - Talk with your healthcare provider to find out about options for acceptable forms of birth control that you may use to prevent pregnancy before, during, and after treatment with lenalidomide capsules.
  - If you had unprotected sex or if you think your birth control has failed, stop taking lenalidomide capsules immediately and call your healthcare provider right away.

If you become pregnant while taking lenalidomide capsules, stop taking it right away and call your healthcare provider. If your healthcare provider is not available, you can call the REMS Call Center at 1-888-423-5436. Healthcare providers and patients should report all cases of pregnancy to:
- FDA MedWatch at 1-800-FDA-1088, and
- The Lenalidomide REMS Program at 1-888-423-5436

There is a pregnancy exposure registry that monitors the outcomes of females who take lenalidomide during pregnancy, or if their male partner takes lenalidomide and they are exposed during pregnancy. You can enroll in this registry by calling the Lenalidomide REMS Program at the phone number listed above.

Lenalidomide can pass into human semen:
- Males, including those who have had a vasectomy, must always use a latex or synthetic condom during any sexual contact with a pregnant female or a female that can become pregnant while taking lenalidomide capsules, during any breaks (interruptions) in your treatment with lenalidomide capsules, and for up to 4 weeks after stopping lenalidomide capsules.
- Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with a female who is or could become pregnant.
- Do not donate sperm while taking lenalidomide capsules, during any breaks (interruptions) in your treatment, and for up to 4 weeks after stopping lenalidomide capsules. If a female becomes pregnant with your sperm, the baby may be exposed to lenalidomide capsules and may be born with birth defects.

Men, if your female partner becomes pregnant, you should call your healthcare provider right away.

- **Low white blood cells (neutropenia) and low platelets (thrombocytopenia).** Lenalidomide capsules causes low white blood cells and low platelets in most people. You may need a blood transfusion or certain medicines if your blood counts drop too low. Your healthcare provider should check your blood counts often especially during the first several months of treatment with lenalidomide capsules, and then at least monthly. Tell your healthcare provider if you develop any bleeding or bruising, during treatment with lenalidomide capsules.
- **Blood clots.** Blood clots in the arteries, veins, and lungs happen more often in people who take lenalidomide capsules. This risk is even higher for people with multiple myeloma who take the medicine dexamethasone with lenalidomide capsules. Heart attacks and strokes also happen more often in people who take lenalidomide capsules with dexamethasone. To reduce this increased risk, most people who take lenalidomide capsules will also take a blood thinner medicine.

Before taking lenalidomide capsules, tell your healthcare provider:
- If you have had a blood clot in the past
- If you have high blood pressure, smoke, or if you have been told you have a high level of fat in your blood (hyperlipidemia)
- About all the medicines you take. Certain other medicines can also increase your risk for blood clots

Call your healthcare provider or get medical help right away if you get any of the following during treatment with lenalidomide capsules:
- **Signs or symptoms of a blood clot in the lung, arm, or leg may include:** shortness of breath, chest pain, or arm or leg swelling
- **Signs or symptoms of a heart attack may include:** chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen), feeling sweaty, shortness of breath, feeling sick or vomiting
- **Signs or symptoms of stroke may include:** sudden numbness or weakness, especially on one side of the body, severe headache or confusion, or problems with vision, speech, or balance

What are lenalidomide capsules?

Lenalidomide capsules are a prescription medicine, used to treat adults with:
- multiple myeloma (MM)
  - in combination with the medicine dexamethasone, or
  - as maintenance treatment after autologous hematopoietic stem cell transplantation (a type of stem cell transplant that uses your own stem cells)
- a condition called myelodysplastic syndromes (MDS). Lenalidomide capsules are for the type of MDS with a chromosome problem where part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS. People with this type of MDS may have low red blood cell counts that require treatment with blood transfusions.
- mantle cell lymphoma (MCL) when the disease comes back or becomes worse after treatment with 2 prior medicines, one of which included bortezomib. MCL is a cancer of a type of white blood cell called lymphocytes that are in the lymph nodes.
- follicular lymphoma (FL) or marginal zone lymphoma (MZL)
  - in combination with a rituximab product, **and**
  - who have previously been treated for their FL or MZL

FL and MZL are types of cancer of white blood cells called B-cell lymphocytes that are found in the lymph nodes and spleen.

Lenalidomide capsules should not be used to treat people who have chronic lymphocytic leukemia (CLL) unless they are participants in a controlled clinical trial.

It is not known if lenalidomide capsule is safe and effective in children.

Who should not take lenalidomide capsules?

Do not take lenalidomide capsules if you:
- **are pregnant, plan to become pregnant, or become pregnant during treatment with lenalidomide capsules.**
  See "What is the most important information I should know about lenalidomide capsules?"
- are allergic to lenalidomide or any of the ingredients in lenalidomide capsules. See the end of this Medication Guide for a complete list of ingredients in lenalidomide capsules.

What should I tell my healthcare provider before taking lenalidomide capsules?

Before you take lenalidomide capsules, tell your healthcare provider about all of your medical conditions, including if you:
- have liver problems
- have kidney problems or receive kidney dialysis treatment
- have thyroid problems
- have had a serious skin rash with thalidomide treatment. You should not take lenalidomide capsules.
- are lactose intolerant. Lenalidomide capsules contains lactose.
- are breastfeeding. Do not breastfeed during treatment with lenalidomide capsules. It is not known if lenalidomide passes into your breast milk and can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Lenalidomide capsules and other medicines may affect each other, causing serious side effects. Talk with your healthcare provider before taking any new medicines. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I take lenalidomide capsules?
- Take lenalidomide capsules exactly as prescribed and follow all the instructions of the Lenalidomide REMS program
- Swallow lenalidomide capsules whole with water 1 time a day. **Do not open, break, or chew your capsules.**
- **Lenalidomide capsules may be taken with or without food.**
- Take lenalidomide capsules at about the same time each day.

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Font Size : 10 Pt.
Color : Black
Track : A19/09/2022, A27/09/2022,
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- Do not open or break lenalidomide capsules or handle them any more than needed.
  - If powder from the lenalidomide capsule comes in contact with your skin, wash the skin right away with soap and water.
  - If powder from the lenalidomide capsule comes in contact with the inside of your eyes, nose, or mouth, flush well with water.
- If you miss a dose of lenalidomide capsules 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 capsules, call your healthcare provider right away.

What should I avoid while taking lenalidomide capsules?

- See "What is the most important information I should know about lenalidomide capsules?"
- **Females: Do not get pregnant and do not breastfeed while taking lenalidomide capsules.**
- **Males: Do not donate sperm** while taking lenalidomide capsules, during any breaks (interruptions) in your treatment, and for up to 4 weeks after stopping lenalidomide capsules.
- **Do not share lenalidomide capsules with other people.** It may cause birth defects and other serious problems.
- **Do not donate blood** while you take lenalidomide capsules, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping lenalidomide capsules. If someone who is pregnant gets your donated blood, her baby may be exposed to lenalidomide capsules and may be born with birth defects.

What are the possible side effects of lenalidomide capsules?

Lenalidomide capsules can cause serious side effects, including:

- See "What is the most important information I should know about lenalidomide capsules?"
- **Increased risk of death in people who have chronic lymphocytic leukemia (CLL).** People with CLL who take lenalidomide capsules have an increased risk of death compared with people who take the medicine chlorambucil. Lenalidomide capsules may cause you to have serious heart problems that can lead to death, including atrial fibrillation, heart attack, or heart failure. You should not take lenalidomide capsules if you have CLL unless you are participating in a controlled clinical trial.
- **Risk of new cancers (malignancies).** An increase in new (second) cancers has happened in patients who received lenalidomide capsules and melphalan, or a blood stem cell transplant, including certain blood cancers, such as acute myelogenous leukemia (AML), and myelodysplastic syndrome (MDS) and certain other types of cancers of the skin and other organs. Talk with your healthcare provider about your risk of developing new cancers if you take lenalidomide capsules. Your healthcare provider will check you for new cancers during your treatment with lenalidomide capsules.
- **Severe liver problems, including liver failure and death.** Your healthcare provider should do blood tests to check your liver function during your treatment with lenalidomide capsules. Tell your healthcare provider right away if you develop any of the following symptoms of liver problems:
  - yellowing of your skin or the white part of your eyes (jaundice)
  - pain on the upper right side of your stomach area (abdomen)
  - dark or brown (tea-colored) urine
  - bleeding or bruising more easily than normal
  - feeling very tired
- **Severe skin reactions and severe allergic reactions** can happen with lenalidomide capsules and may cause death.

  Call your healthcare provider right away if you develop any of the following signs or symptoms during treatment with lenalidomide capsules:
  - a red, itchy, skin rash
  - peeling of your skin or blisters
  - severe itching
  - fever

Get emergency medical help right away if you develop any of the following signs or symptoms during treatment with lenalidomide capsules:

- swelling of your lips, mouth, tongue, or throat
- raised red areas on your skin (hives)
- trouble breathing or swallowing
- a very fast heartbeat
- you feel dizzy or faint

- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure and sometimes death. Your healthcare provider may do blood tests to check you for TLS.
- **Worsening of your tumor (tumor flare reaction)** can happen with lenalidomide capsules and may cause death**.** Tell your healthcare provider if you get any of these symptoms of tumor flare reaction during treatment with lenalidomide capsules: tender swollen lymph nodes, low grade fever, pain, or rash.

Your healthcare provider may tell you to decrease your dose, temporarily stop or permanently stop taking lenalidomide capsules if you develop certain serious side effects during treatment with lenalidomide capsules.

- **Thyroid problems.** Your healthcare provider may check your thyroid function before you start taking lenalidomide capsules and during treatment with lenalidomide capsules.
- **Risk of Early Death in MCL.** In people who have Mantle Cell Lymphoma (MCL), there may be a risk of dying sooner (early death) when taking lenalidomide capsules. Talk with your healthcare provider about any concerns and possible risk factors.

The most common side effects of lenalidomide capsules include:

- diarrhea
- swelling of your arms, hands, legs, feet and skin
- upper respiratory tract infection or bronchitis
- rash
- sleep problems (insomnia)
- inflammation of the stomach and intestine ("stomach flu")
- nausea
- headache
- nose bleed
- constipation
- muscle cramps or spasms
- shaking or trembling (tremor)
- tiredness or weakness
- shortness of breath
- joint aches
- fever
- cough, sore throat, and other symptoms of a cold
- pain in your back or stomach-area (abdomen)
- itching

These are not all the possible side effects of lenalidomide capsules.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store lenalidomide capsules?

- Store lenalidomide capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Return any unused lenalidomide capsules to Sun Pharmaceutical Industries, Inc. or your healthcare provider.

Keep lenalidomide capsules and all medicines out of the reach of children.

General information about the safe and effective use of lenalidomide capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take lenalidomide capsules for conditions for which it was not prescribed. Do not give lenalidomide capsules to other people, even if they have the same symptoms you have. It may harm them and may cause birth defects.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about lenalidomide capsules that is written for health professionals.

What are the ingredients in lenalidomide capsules?

Active ingredient: lenalidomide

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

The green imprinting ink contains FD&C Blue# 2 Aluminum Lake, ferric oxide yellow, propylene glycol, shellac, strong ammonia solution, and titanium dioxide (2.5 mg, 10 mg and 20 mg). The black imprinting ink contains ferrosoferric oxide, potassium hydroxide, propylene glycol, shellac, and strong ammonia solution (5 mg and 25 mg). The blue imprinting ink contains FD&C Blue# 2 Aluminum Lake, propylene glycol, shellac, and strong ammonia solution (15 mg and 20 mg). The yellow imprinting ink contains ferric oxide yellow, propylene glycol, shellac, and strong ammonia solution (10 mg).

For more information, call 1-888-423-5436 or go to www.lenalidomiderems.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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