

Lenalidomide (Revlimid®)

About This Drug

Lenalidomide is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak (fatigue), and raise your risk of bleeding
- Nausea
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Inflammation of your stomach and/or intestines
- Pain in your abdomen
- Fever
- Tiredness and weakness
- Swelling of your legs, ankles and/or feet
- Decreased appetite (decreased hunger)
- Muscle cramps/spasms
- Back pain
- Pain in your joints
- Headache
- Feeling dizzy
- Tremor
- Trouble sleeping
- Nosebleed
- Upper respiratory infection, bronchitis
- Inflammation of the nasal passages and throat
- Trouble breathing
- Cough
- Rash and itching

Note: Each of the side effects above was reported in 15% or greater of patients treated with lenalidomide. Not all possible side effects are included above.

Warnings and Precautions

- Blood clots and events such as stroke and heart attack. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.
- Severe bone marrow suppression.
- Changes in your liver function, which may cause liver failure and be life-threatening.
- Tumor lysis syndrome: This drug may act on the cancer cells very quickly. This may affect how your kidneys work and can be life-threatening.
- Changes in your thyroid function
- Severe allergic skin reaction which may be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- This drug may raise your risk of getting a second cancer.
- You may develop a syndrome called tumor flare reaction. You may have painful lymph nodes, enlarged spleen, fever and a rash.
- This drug may make it more difficult to collect your stem cells if an autologous stem cell transplant is part of your treatment plan.
- There is a rare increased risk of death in patients with chronic lymphocytic leukemia and a risk of early death (dying sooner) in patient with mantle cell lymphoma.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- You will need to sign up for a special program called Revlimid® REMS when you start taking this drug. Your nurse will help you get started.
- Do not donate blood during your treatment and for 4 weeks after your treatment.
- Men should not donate sperm during your treatment and for 4 weeks after your treatment because this drug is present in semen and may badly harm a baby.

How to Take Your Medication

- Swallow the medicine whole with water, with or without food. Do not chew, break, or open it.
- Take this medicine at the same time each day
- **Missed dose:** If you miss a dose, take it as soon as you think about it ONLY if it has been less than 12 hours since your regular time. If it has been more than 12 hours, skip the missed dose and contact your physician. Take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- If you vomit a dose, take your next dose at the regular time.

- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- If you get any of the content of a broken capsules on your skin, you should wash the area of the skin well with soap and water right away. Call your doctor if you get a skin reaction.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- If you are dizzy, get up slowly after sitting or lying.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- Drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- Include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- To help with decreased appetite, eat small, frequent meals.
- Eat high caloric food such as pudding, ice cream, yogurt and milkshakes.

- If you get a rash, do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you are having trouble sleeping, talk to your nurse or doctor on tips to help you sleep better.
- If you have a nose bleed, sit with your head tipped slightly forward. Apply pressure by lightly pinching the bridge of your nose between your thumb and forefinger. Call your doctor if you feel dizzy or faint or if the bleeding doesn't stop after 10 to 15 minutes.
- Moisturize your skin several times a day
- Avoid sun exposure and apply sunscreen routinely when outdoors

Food and Drug Interactions

- There are no known interactions of lenalidomide with food.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) you are taking before starting this medicine as there are known drug interactions with lenalidomide. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- There are known interactions of lenalidomide with blood-thinning medicine such as warfarin. Ask your doctor what precautions you should take.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Your leg or arm is swollen, red, warm and/or painful
- Headache that does not go away
- Nose bleed that doesn't stop bleeding after 10-15 minutes
- Painful lymph nodes
- Wheezing and/or trouble breathing
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or

sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**

- Coughing up yellow, green, or bloody mucus
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Loose bowel movements (diarrhea) 4 times a day or loose bowel movements with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Trouble falling or staying asleep
- Pain in your abdomen that does not go away
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of your legs, ankles and/or feet
- Unexplained weight gain
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Pain that does not go away, or is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- A new rash or itching that is not relieved by prescribed medicines
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of tumor lysis: Confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures.
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of child-bearing potential should use 2 effective methods of birth control, one of which, must be a *highly* effective method of birth control, beginning at least 4 weeks before treatment starts, during your cancer treatment, including dose interruptions, and for at least 4 weeks after treatment. A highly effective method of birth control includes tubal ligation, intra-uterine device (IUD), hormonal (birth control pills, injections, patch and/or implants) or a partner's vasectomy. Let your doctor know right away if you think you may be pregnant
- Two negative pregnancy tests are required in women of child-bearing potential prior to starting treatment.
- You will need to have routine pregnancy tests while you are taking this drug.
- Men with female partners of child-bearing potential should use effective methods of birth control during your cancer treatment and for at least 4 weeks after your cancer treatment. You should always wear a condom even if you have undergone a successful vasectomy. Let your doctor know right away if you think you may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.

- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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