

Lenalidomide (Revlimid)

About This Medicine

LENALIDOMIDE (len a LID oh mide) treats blood and bone marrow cancers. It works by slowing down the growth of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

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, 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
- Pain in your joints
- Back pain
- Feeling dizzy
- Headache
- Tremors (shaking in parts or all of the body)
- Trouble sleeping
- Nosebleed
- Upper respiratory tract infection, inflammation in your airway
- 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 people treated with lenalidomide. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

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 medicine 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. Sometimes, a serious and life-threatening reaction to this medicine can happen that can cause a skin rash, along with problems with your organs, swollen lymph nodes, fever and higher than normal white blood cells.
- This medicine may raise your risk of getting another cancer, such as acute myeloid leukemia and myelodysplastic syndrome
- You may develop a syndrome called tumor flare reaction which may be life-threatening. You may have painful lymph nodes, enlarged spleen, fever, and a rash.
- This medicine may make it more difficult to collect your stem cells if a 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.
- Allergic reactions, including anaphylaxis, are rare but may happen in some people. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment.**

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

Important Information

- This medicine is part of special program which helps make sure it is used safely (Risk Evaluation and Mitigation Strategy [REMS] program). As part of this program, you may be asked to read safety information or complete certain tests while taking it. Your care team will provide you with more information
- If you can become pregnant, two negative pregnancy tests are required prior to starting treatment. Routine pregnancy tests are also required during treatment.



- Do not donate blood during your treatment and for 4 weeks after stopping your treatment.
- Do not donate sperm during treatment and for 4 weeks after stopping your treatment because this medicine is present in semen.

How to Take Your Medicine

- Swallow the medicine whole with water, with or without food. Do not chew, break, or open it.
- Take this medicine at about 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 you normally take the missed dose. If it has been more than 12 hours, skip the missed dose. 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.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- If you get the contents of a broken capsule on your skin, you should wash the area of the skin well with soap and water right away. Call your care team if you get a skin reaction.
- If you get the contents of a broken capsule in your eyes, nose, or mouth, flush well with water.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **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 medicine 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 care team 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 care team 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 care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.



- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- 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 care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- If you get a rash, do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- If you have a nosebleed, sit with your head tipped slightly forward. Apply pressure by lightly pinching the bridge of your nose between your thumb and forefinger. Call your care team if you feel dizzy or faint or if the bleeding does not stop after 10 to 15 minutes.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.

Food and Medicine Interactions

- There are no known interactions of lenalidomide with food.
- Check with your care team 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 medicine interactions with lenalidomide. Also, check with your care team 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 care team what precautions you should take.

When to Call Your Care Team

Call your care team 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 or weakness that interferes with your daily activities



- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Headache that does not go away
- Tremors
- Nosebleed that does not stop bleeding after 10-15 minutes
- 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.**
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Cough that is bothersome
- Coughing up yellow, green, or bloody mucus
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea 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
- Your leg is swollen, red, warm, and/or painful
- Swollen lymph nodes in your neck and/or armpits
- 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 and/or itching or a rash that is not relieved by prescribed medicines
- Signs of low thyroid function: tiredness, unexplained weight gain, hair loss, dry skin, constipation, increased sensitivity to cold
- Signs of increased thyroid function: unexplained weight loss, sweating, irritability, feeling that your heart is beating fast or in a not normal way (palpitations)
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, 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



Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, you must commit to abstain from heterosexual intercourse or 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 stopping 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. You should follow these recommendations even if you have a history of infertility. Stop taking lenalidomide immediately and let your care team know right away if you think you may be pregnant, miss your menstrual period, or experience unusual menstrual bleeding.
- If you can get your partner pregnant, you should use effective methods of birth control during your cancer treatment, including dose interruptions, and for at least 4 weeks after stopping treatment. You should always wear a condom even if you have undergone a successful vasectomy. Tell your care team right away if you think you think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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