Lenalidomide (Revlimid®)

Pronounced: LEN-a-LID-oh-mide

Classification: Immunomodulatory Agent

About Lenalidomide (Revlimid®)

Lenalidomide is a type of "immunomodulatory agent", meaning it works by affecting the immune system. It appears to work in several ways, including inhibiting the formation of blood vessels, which tumors use to get nutrients needed to survive and grow. This is known as anti-angiogenesis. It also interferes with chemicals necessary for the growth of tumors and can cause cell death.

How to Take Lenalidomide

Lenalidomide is taken by mouth, in capsule form, with a dosing schedule to be determined by your provider. It can be taken with or without food. Take lenalidomide at around the same time every day. Swallow the capsules whole; do not break, chew or open the capsules. If you touch a broken capsule or come into contact with the medicine inside, wash the area with soap and water.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

If you miss a dose and it has been less than 12 hours since your regular dose time, take it as soon as you remember. If it has been more than 12 hours, skip the dose. Do not take 2 doses at once to make up for a missed dose.

Lenalidomide (Revlimid®) REMS Program

In order to receive lenalidomide, patients will need to participate in a program called REMS (Risk Evaluation and Mitigation Strategy). This program educates healthcare professionals and patients about the dangers of lenalidomide exposure to a fetus. This exposure can cause serious birth defects and patients taking the medication will need to use two reliable forms of birth control. This includes men taking lenalidomide because it is present in sperm. The REMS program limits who can prescribe and dispense the medication. Patients will also need to complete a survey and safety agreement before starting the drug and every month they are taking it. Important safety reminders:

- Women should not become pregnant for 4 weeks before therapy, during therapy, and for 4 weeks after therapy is stopped.
- Women must agree to use 2 forms of reliable birth control or total abstinence during this time.
- A negative pregnancy test 10 to 14 days prior to treatment, within 24 hours prior to treatment, weekly during the first 4 weeks, and every 4 weeks thereafter is required for women of childbearing potential
- Men should not father a child for 4 weeks before therapy, during therapy, or for 4 weeks after therapy is stopped.
- Men must use a condom during any sexual contact during this time, even if they have had a vasectomy with women of childbearing potential and for up to 28 days after stopping treatment.
- Any pregnancy (in women taking the medication OR partners of men who take the medication) should be reported to your oncology team right away.
- Treatment must be stopped immediately for a missed period, abnormal pregnancy test, or abnormal menstrual bleeding; refer to a reproductive toxicity specialist if pregnancy occurs during treatment
- Do not donate blood or sperm during therapy and for at least 1 month after stopping therapy.
Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your pharmaceutical insurance coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Lenalidomide

There are a number of things you can do to manage the side effects of lenalidomide. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Blood Clots, Stroke, and Heart Attack**

Lenalidomide can increase the risk of blood clots, stroke, and heart attack. If you experience symptoms of these problems, you should contact your healthcare provider immediately or go to an emergency room. Symptoms can include: swelling, redness or pain in an extremity, chest pain or pressure, pain in your arm, back, neck or jaw, shortness of breath, numbness or weakness on one side of the body, trouble talking, confusion or mental status changes. Let your care team know if you have a history of previous blood clots, as you may require preventive medication.

**Low White Blood Cell Count (Leukopenia or Neutropenia)**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your doctor or nurse before scheduling dental appointments or procedures.
- Ask your doctor or nurse before you, or someone you live with has any vaccinations.

**Low Red Blood Cell Count (Anemia)**
Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the **red cell count is low**, you may feel tired or weak. You should let your doctor or nurse know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Low Platelet Count (Thrombocytopenia)**
Platelets help your blood clot, so when the **count is low** you are at a higher risk of bleeding. Let your doctor or nurse know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin®, Aleve®, Advil®, etc. as these can all increase the risk of bleeding. Unless your healthcare team tells you otherwise, you may take acetaminophen (Tylenol).
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**Diarrhea**
Your oncology team can recommend medications to relieve diarrhea. Also, try eating **low-fiber**, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Fatigue**
Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Constipation**
There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Fluid Retention / Swelling**
Some patients may develop fluid retention, which can cause swelling in the feet and/or ankles or face or gain weight. Fluid can also build up in the lungs and cause you to feel short of breath. Notify your healthcare team if you have any swelling, unexpected weight gain or shortness of breath.

**Muscle and Joint Pain/Aches**
Your doctor or nurse can recommend medication and other strategies to relieve pain.

**Shortness of Breath**
Notify your healthcare provider right away if you develop any new or worsening symptoms, including shortness of breath, trouble breathing, cough or fever.

**Skin Changes**
Some patients may develop a rash, very dry or itchy skin. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your doctor or nurse can recommend a topical medication if itching is bothersome. If your
skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your healthcare provider of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

**Decrease in Appetite**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Less common, but important side effects can include:**

- **Liver Toxicity:** This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. Notify your care team if you notice yellowing of the skin or eyes, your urine appears dark or brown, you have pain in your abdomen, or you notice you bruise or bleed easily, as these can be signs of liver toxicity.

- **Allergic Reactions:** Severe allergic or skin reactions can occur with this medication. Call your care team or go to the emergency room if you experience symptoms of an allergic reaction, including: swelling of the lips, mouth, tongue or throat, or have difficulty breathing. Notify your care team if you develop any skin rash.

- **Tumor Flare:** While taking this medication, you can experience a "tumor flare" which can result in symptoms of the cancer getting temporarily worse. Notify your care team if you develop any swollen lymph nodes, fever or pain.

- **Secondary Cancers:** A secondary cancer is one that develops as a result of cancer treatment for another cancer. This is quite rare, but you should be aware of the risk. In most cases, a secondary cancer related to chemotherapy is a blood cancer (leukemia, lymphoma). This can occur years after treatment. This is most often associated with repeated treatments or high doses. Your provider will monitor your labs closely. Consider having a complete blood count with differential checked annually by your healthcare provider if you received high risk therapies.

- **Tumor Lysis Syndrome:** If there are a large amount of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

**Reproductive Concerns**

As discussed above, exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Women should not become pregnant for four weeks prior to starting treatment, during treatment or for four weeks after treatment is complete. A woman should use two forms of birth control during this time period. Men should not father a child during treatment or for four weeks after treatment is complete. A man should use a condom during sexual contact during this time period even if he has had a vasectomy. Report pregnancy any suspected to your provider immediately. Do not breastfeed while taking this medication.