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2. Lenalidomide

# Lenalidomide 🖘

Generic name: lenalidomide Brand name: Revlimid

**Dosage form:** capsules (2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg) **Drug classes:** Miscellaneous antineoplastics, Other immunosuppressants

Medically reviewed by Melisa Puckey, BPharm. Last updated on Apr 22, 2024.

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## What is Lenalidomide?

Lenalidomide is a medication used to treat types of multiple myeloma, mantle cell lymphoma, follicular lymphoma, marginal zone lymphoma, and anemia in myelodysplastic syndromes (MDS) in adults. Lenalidomide helps to slow cancer growth, block new blood vessel growth in tumors, and help the immune system fight cancer. This medicine is available as capsules that are taken once a daily.

Lenalidomide received FDA approval on December 27, 2005, with the brand name Revlimid. This medicine is only available through a restricted distribution program called the Lenalidomide REMS program, as it may cause birth defects or embryo-fetal death.

## What is Lenalidomide used for?

Lenalidomide is used for specific adult patients with:

**Multiple Myeloma** in combination with dexamethasone. Also, for multiple myeloma maintenance therapy in patients who have had an autologous hematopoietic stem cell transplantation (auto-HSCT).

**Myelodysplastic Syndromes with transfusion-dependent anemia** due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

Mantle Cell Lymphoma (MCL) has relapsed or progressed after two prior therapies, one of which included bortezomib.

Previously treated Follicular Lymphoma (FL), used in combination with a rituximab product.

Previously treated Marginal Zone Lymphoma (MZL), used in combination with combination with a rituximab product.

Lenalidomide is not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials.

## Lenalidomide side effects

Common Lenalidomide side effects may include:

- cold symptoms such as stuffy nose, sneezing, and sore throat;
- · sleep problems, tiredness;
- · weakness;
- · headache:
- tremors;
- · nosebleed;
- · muscle cramps;
- · joint pain;
- · shortness of breath;
- fever, cough, tiredness;
- itching, rash, swelling, or
- stomach pain, nausea, vomiting, diarrhea, constipation.

#### Serious Lenalidomide side effects.

Get emergency medical help if you have signs of an allergic reaction (hives, difficulty breathing, swelling in your face or throat) or a severe skin reaction (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Lenalidomide may cause serious side effects. Call your doctor at once if you have:

- signs of a stroke or blood clot sudden numbness or weakness, severe headache, problems with speech or vision, shortness of breath, swelling or redness in your arm or leg;
- heart attack symptoms chest pain or pressure, pain spreading to your jaw or shoulder, sweating;
- liver problems upper stomach pain, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- low blood cell counts fever, chills, swollen gums, mouth sores, skin sores, easy bruising, unusual bleeding;
- signs of a tumor getting worse swollen glands, low fever, rash, or pain; or
- signs of tumor cell breakdown lower back pain, blood in your urine, little or no urinating, numbness or tingly feeling around your mouth, muscle weakness or tightness, feeling short of breath, confusion, fainting.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

**1** Lenalidomide side effects (more detail)

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# **Warnings**

Never use lenalidomide if you are pregnant. Even one dose of lenalidomide can cause severe, life-threatening birth defects or death of a baby if the mother or the father is taking this medicine at the time of conception or during pregnancy.

Use birth control to prevent pregnancy, whether you are a man or a woman.

For women: Use two forms of birth control, beginning 4 weeks before you start taking lenalidomide and ending 4 weeks after you stop taking it. See the 'Before taking this medicine' section for more information.

For men: Use a condom to prevent pregnancy during your treatment and for up to 4 weeks after your treatment ends. See the 'Before taking this medicine' section for more information.

Lenalidomide may cause blood clots. Stop using this medicine and call your doctor at once if you have symptoms such as sudden numbness, severe headache, problems with vision or speech, chest pain, shortness of breath, coughing up blood, or swelling in your arm or leg.

Lenalidomide can lower blood cells that help your body fight infections and help your blood clot. Call your doctor if you have unusual bruising or bleeding or signs of infection (fever, chills, body aches). You will need frequent blood tests while you are taking lenalidomide.

# Before taking this medicine

You should not use lenalidomide if you are allergic to lenalidomide.

To make sure lenalidomide is safe for you, tell your doctor if you have ever had:

- an allergic reaction to thalidomide;
- kidney disease (or if you are on dialysis);
- liver disease;
- a blood clots or stroke;
- high blood pressure, high cholesterol or triglycerides;
- · a thyroid disorder;
- lactose intolerance; or
- · if you smoke.

Using lenalidomide may increase your risk of developing other types of cancer, such as leukemia or lymphoma. Talk with

your doctor about your specific risk.

## **Pregnancy**

Lenalidomide can cause severe, life-threatening birth defects or death of a baby if the mother or the father is taking this medicine at the time of conception or during pregnancy. Even one dose of lenalidomide can cause major birth defects in the baby's arms and legs, bones, ears, eyes, face, and heart. Never use lenalidomide if you are pregnant. Tell your doctor right away if your period is late while taking lenalidomide.

**For Women:** If you have not had a hysterectomy, you will be required to use two reliable forms of birth control, beginning 4 weeks before you start taking lenalidomide and ending 4 weeks after you stop taking it. Even women with fertility problems are required to use birth control while taking this medicine. You must also have a negative pregnancy test 10 to 14 days before treatment and again 24 hours before. While you are taking lenalidomide, you will have a pregnancy test every 2 to 4 weeks.

The birth control method you use must be proven highly effective, such as birth control pills, an intrauterine device (IUD), a tubal ligation, or a sexual partner's vasectomy. The extra form of birth control you use must be a barrier method such as a latex condom, a diaphragm, or a cervical cap.

Stop using lenalidomide and call your doctor at once if you quit using birth control, if your period is late, or if you think you might be pregnant. Not having sexual intercourse (abstinence) is the most effective method of preventing pregnancy.

**For Men:** If a man fathers a baby while using lenalidomide, the baby may have birth defects. Use a condom to prevent pregnancy during your treatment and for up to 4 weeks after your treatment ends. You must agree in writing to always use latex condoms when having sex with a woman who is able to get pregnant, even if you have had a vasectomy. Contact your doctor if you have had unprotected sex, even once, or if you think your female sexual partner may be pregnant.

## **Breastfeeding**

You should not breastfeed while using lenalidomide.

**1** Lenalidomide pregnancy and breastfeeding warnings (more detail)

## How should I take lenalidomide?

Take the medicine at the same time each day. You may take lenalidomide with or without food.

Take each dose with a full glass of water. Swallow the capsule whole without breaking it open.

Lenalidomide can increase your risk of bleeding or infection. Your blood will need to be tested often.

Medicine from an open capsule can be dangerous if it gets on your skin. If this occurs, wash your skin with soap and water. Ask your doctor or pharmacist how to handle and dispose of a broken capsule safely.

Take lenalidomide exactly as prescribed by your doctor. Follow all directions on your prescription label. Do not take this medicine in larger or smaller amounts or longer than recommended. Never share this medicine with another person, even if they have the same disorder you have.

# **Lenalidomide Dosing information**

## **Usual Adult Lenalidomide Dose for Multiple Myeloma**

Use: Multiple Myeloma in combination with dexamethasone

**Dose:** 25 mg orally once a day on Days 1 to 21 of repeated 28-day cycles until disease progression or unacceptable toxicity

#### Use: Maintenance therapy for Multiple Myeloma following auto-HSCT

Dose: 10 mg once a day continuously (Days 1 to 28 of repeated 28-day cycles) for 3 cycles, then increase to 15 mg once a day if tolerated until disease progression or unacceptable toxicity.

#### Comments:

For patients who are not eligible for auto-HSCT, therapy should continue until disease progression or unacceptable toxicity.

For patients who are eligible for auto-HSCT, hematopoietic stem cell mobilization should occur within 4 cycles. Following auto-HSCT, initiate maintenance therapy after adequate hematologic recovery (ANC 1000/mcL or more AND/OR platelet count 75,000/mcL or more).

Consult the manufacturer's product information for dexamethasone dosing recommendations.

## **Usual Adult Lenalidomide Dose for Myelodysplastic Disease:**

**Dose:** 10 mg orally once a day; therapy is continued or modified based on clinical and laboratory findings until disease progression or unacceptable toxicity

**Use:** Treatment of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

## Usual Adult Lenalidomide Dose for Lymphoma:

#### Follicular Lymphoma or Marginal Zone Lymphoma:

**Dose:** 20 mg orally once a day on Days 1 through 21 of repeated 28-day cycles for up to 12 cycles in combination with a rituximab product.

**Use:** In combination with a rituximab product for the treatment of previously treated follicular lymphoma (FL). In combination with a rituximab product for the treatment of previously treated marginal zone lymphoma (MZL).

#### Mantel Cell Lymphoma:

**Dose:** 25 mg orally once a day on Days 1 to 21 of repeated 28-day cycles until disease progression or unacceptable toxicity; treatment is continued, modified, or discontinued based on clinical and laboratory findings.

**Use:** The treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after 2 prior therapies, one of which included bortezomib.

Revlimid is available in 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg capsules.

Detailed Lenalidomide dosage information

# What happens if I miss a dose?

Take the missed dose as soon as you remember. If you are more than 12 hours late, skip the missed dose. Do not take extra medicine to make up for the missed dose.

# What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What to avoid

You must not donate blood or sperm while you are using Revlimid (lenalidomide), and for at least 4 weeks after your last dose. Avoid exposing another person to your blood or semen through casual or sexual contact.

This medicine can pass into body fluids (urine, feces, vomit). Caregivers should wear rubber gloves while cleaning up a patient's body fluids, handling contaminated trash or laundry or changing diapers. Wash hands before and after removing gloves. Wash soiled clothing and linens separately from other laundry.

# What other drugs will affect lenalidomide?

Tell your doctor if you also use pembrolizumab (Keytruda).

If you use hormonal birth control (pills, implants, injections) to prevent pregnancy. There are certain drugs that can make hormonal birth control less effective in your body. Tell your doctor about all other medicines you use. You may need to replace your hormonal birth control method with another effective form of contraception.

Other drugs may interact with lenalidomide, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

1 Lenalidomide drug interactions (more detail)

## Does lenalidomide interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



# **Revlimid Package Insert**

Review the Revlimid Package Insert for more detailed information about this medicine. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

# **Handling and Disposal**

Care should be exercised in the handling of this medicine. Capsules should not be opened or broken. If powder from capsules contacts the skin, wash the skin immediately and thoroughly with soap and water. If lenalidomide contacts the mucous membranes, flush thoroughly with water. Procedures for the proper handling and disposal of anticancer drugs should be considered. Several guidelines on the subject have been published. Dispense no more than a 28-day supply.

# Ingredients

Active ingredient: lenalidomide

**Revlimid Inactive ingredients:** lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

The 5 mg and 25 mg capsule shells contain gelatin, titanium dioxide, and black ink.

The 2.5 mg and 10 mg capsule shells contain gelatin, FD&C blue #2, yellow iron oxide, titanium dioxide, and black ink.

The 15 mg capsule shell contains gelatin, FD&C blue #2, titanium dioxide, and black ink.

The 20 mg capsule shell contains gelatin, FD&C blue #2, yellow iron oxide, titanium dioxide and black ink.

# **Storage**

Store at 20°C - 25°C (68°F - 77°F)

# Company

Bristol-Myers Squibb Company Princeton, NJ 08543 USA.

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#### References

1. Revlimid Product Label

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## **Patient resources**

#### Other brands

Revlimid

## **Professional resources**

- Lenalidomide monograph
- Lenalidomide (FDA)

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## Related treatment guides

- Anemia
- Follicular Lymphoma
- Lymphoma
- Mantle Cell Lymphoma

## **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

## **Availability**

Rx Prescription only

## **Pregnancy & Lactation**

প্ Risk data available

## **CSA Schedule\***

N/A Not a controlled drug

## **Approval History**

□ Drug history at FDA

## **User Reviews & Ratings**

#### **Related News**

U.S. FDA Approves Pfizer's Adcetris Combination Regimen for the Treatment of Relapsed / Refractory Diffuse Large B-Cell Lymphoma

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