



Revlimid[®]
(lenalidomide) capsules
2.5 · 5 · 10 · 15 · 20 · 25 mg



Photo not of actual patients.

TAKE YOUR NEXT STEP WITH REVLIMID

A GUIDE FOR PATIENTS WITH RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA

What is REVLIMID[®] (lenalidomide)?

REVLIMID is a prescription medicine used to treat adults with mantle cell lymphoma (MCL) when the disease comes back or becomes worse after treatment with two 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.

REVLIMID 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 REVLIMID is safe and effective in children.

REVLIMID is only available through a restricted distribution program, REVLIMID REMS[®].

WARNING: Risk to unborn babies, risk of low blood counts and blood clots.

Please see accompanying full [Prescribing Information](#), including **Boxed WARNINGS** and **Medication Guide**, for REVLIMID, and **Important Safety Information** throughout the guide.

GETTING STARTED ON REVLIMID

HOW CAN THIS GUIDE HELP?

When starting treatment with REVLIMID® (lenalidomide), you will probably have questions about what to expect. This guide serves as an additional source of information to help you understand your treatment. Your treatment team—doctors, nurses, and other healthcare professionals—is your first source of information and can address many of your questions. Use the back cover of this guide to write down questions you would like to discuss with your treatment team.



2 Photo not of actual patients.

WHAT IS MANTLE CELL LYMPHOMA?

Mantle cell lymphoma (MCL) is a cancer of a type of **white blood cell** called **lymphocytes** that are found in the **lymph nodes**, the bloodstream, and other tissues.

Definitions

Lymph node

Also called a lymph gland. A rounded mass of lymphatic tissue that is surrounded by a capsule of connective tissue. Lymph nodes filter lymph (lymphatic fluid), and they store lymphocytes (a type of white blood cell). They are located along lymphatic vessels.

Lymphocyte

A type of white blood cell. Lymphocytes have a number of roles in the immune system, including the production of substances that fight infections and other diseases.

Mantle cell lymphoma

A fast-growing type of B-cell non-Hodgkin lymphoma that usually occurs in middle-aged or older adults. It is marked by small- to medium-size cancer cells that may be in the lymph nodes, spleen, bone marrow, blood, or gastrointestinal system.

White blood cell

A type of cell that is found in the blood and lymph tissue that helps fight infections and diseases. Lymphocytes are a type of white blood cell.

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about REVLIMID® (lenalidomide)?

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

REVLIMID 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 REVLIMID.

REVLIMID is similar to the medicine thalidomide which is known to cause severe life-threatening birth defects. REVLIMID has not been tested in pregnant females. REVLIMID has harmed unborn animals in animal testing.

Females must not get pregnant:

- For at least 4 weeks before starting REVLIMID
- While taking REVLIMID
- During any breaks (interruptions) in your treatment with REVLIMID
- For at least 4 weeks after stopping REVLIMID

Females who can become pregnant:

- Must 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 2 different forms of effective 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 REVLIMID.
- Talk with your healthcare provider to find out about options for effective forms of birth control that you may use to prevent pregnancy before, during, and after treatment with REVLIMID.
- If you had unprotected sex or if you think your birth control has failed, stop taking REVLIMID immediately and call your healthcare provider right away.

If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider. If your healthcare provider is not available, you can call Celgene Customer Care 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
- Celgene Corporation at 1-888-423-5436.

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

REVLIMID 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 REVLIMID, during any breaks (interruptions) in your treatment with REVLIMID, and for up to 4 weeks after stopping REVLIMID.
- 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 REVLIMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID. If a female becomes pregnant with your sperm, the baby may be exposed to REVLIMID and may be born with birth defects.

Men: If a female becomes pregnant with your sperm, you should call your HCP right away.

- **Low white blood cells (neutropenia) and low platelets (thrombocytopenia).** REVLIMID 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 REVLIMID, and then at least monthly. Tell your healthcare provider if you develop any bleeding or bruising during treatment with REVLIMID.
- **Blood clots.** Blood clots in the arteries, veins, and lungs happen more often in people who take REVLIMID. This risk is even higher for people with multiple myeloma who take the medicine dexamethasone with REVLIMID. Heart attacks and strokes also happen more often in people who take REVLIMID with dexamethasone. To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

Before taking REVLIMID, 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); and
- about all the medicines you take. Certain other medicines can also increase your risk for blood clots

Please see accompanying full [Prescribing Information](#), including **Boxed WARNINGS** and [Medication Guide](#), for REVLIMID, and Important Safety Information throughout the guide.



HOW TO TAKE REVLIMID

BEFORE STARTING TREATMENT

Your healthcare provider (HCP) will monitor you before and during treatment by performing tests including, but not limited to: pregnancy status, liver function, blood cell counts, blood clots, skin reactions, and thyroid function. Talk to your HCP about the frequency of these tests and any other tests that may be recommended.

Your HCP will explain the possible side effects you may expect to experience with your treatment. Information related to these side effects may be found throughout this brochure in the Important Safety Information sections. Your HCP will also explain the REVLIMID® (lenalidomide) restricted distribution program called REVLIMID REMS® to you.

ONCE-DAILY ORAL DOSING

REVLIMID is a once-daily pill taken at home or wherever is convenient for you.



(Capsules shown are not actual size.)

Take REVLIMID exactly as prescribed by your HCP. Your HCP will monitor for side effects and adjust or interrupt your dose as necessary.

This chart provides an example of when you should take REVLIMID.

- Take REVLIMID every day for 21 days, as shown, for repeating 28-day cycles
– Your HCP will let you know what dose is best for you and adjust it as needed

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
REVLIMID	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■							

IMPORTANT THINGS TO REMEMBER WHEN TAKING REVLIMID

- Swallow REVLIMID capsules whole, with water, 1 time a day. **Do not open, break, or chew your capsules**
- **REVLIMID may be taken with or without food**
- Take REVLIMID at about the same time each day
- Do **not** open or break the REVLIMID capsules or handle them any more than needed. If you touch a broken REVLIMID capsule or the medicine in the capsule, wash the area of your body right away with soap and water. If powder from the REVLIMID capsule comes in contact with the inside of your eyes, nose, or mouth, flush well with water
- If you miss a dose of REVLIMID 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 REVLIMID, call your healthcare provider right away
- **Do not share REVLIMID with other people.** It may cause birth defects and other serious problems

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IMPORTANT SAFETY INFORMATION (CONTINUED)

What is the most important information I should know about REVLIMID® (lenalidomide)? (continued)

Call your healthcare provider or get medical help right away if you get any of the following during treatment with REVLIMID:

- **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

Who should not take REVLIMID?

Do not take REVLIMID if you:

- are pregnant, plan to become pregnant, or become pregnant during treatment with REVLIMID. See “What is the most important information I should know about REVLIMID?”
- are allergic to lenalidomide or any of the ingredients in REVLIMID. See the Medication Guide for a complete list of ingredients in REVLIMID.

What should I tell my healthcare provider before taking REVLIMID?

Before you take REVLIMID, 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 REVLIMID.
- are lactose intolerant. REVLIMID contains lactose.
- are breastfeeding. Do not breastfeed during treatment with REVLIMID. It is not known if REVLIMID 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. REVLIMID 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 REVLIMID?

Take REVLIMID exactly as prescribed and follow all the instructions of the REVLIMID REMS program

- Swallow REVLIMID capsules whole, with water, 1 time a day. **Do not open, break, or chew your capsules.**
- **REVLIMID may be taken with or without food.**
- Take REVLIMID at about the same time each day.
- Do not open the REVLIMID capsules or handle them any more than needed. If powder from the REVLIMID capsule comes in contact with:
 - your skin, wash the skin right away with soap and water.
 - inside of your eyes, nose, or mouth, flush well with water.
- If you miss a dose of REVLIMID 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 REVLIMID, call your healthcare provider right away.

What should I avoid while taking REVLIMID?

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

What are the possible side effects of REVLIMID?

REVLIMID can cause serious side effects, including:

- See “What is the most important information I should know about REVLIMID?”
- **Increased risk of death in people who have chronic lymphocytic leukemia (CLL).** People with CLL who take REVLIMID have an increased risk of death compared with people who take the medicine chlorambucil. REVLIMID may cause you to have serious heart problems

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IMPORTANT SAFETY INFORMATION (CONTINUED)

What are the possible side effects of REVLIMID® (lenalidomide)? (continued)

that can lead to death, including atrial fibrillation, heart attack, or heart failure. You should not take REVLIMID 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 REVLIMID and melphalan, or a blood stem cell transplant, including certain blood cancers, such as acute myelogenous leukemia (AML), myelodysplastic syndromes (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 REVLIMID. Your healthcare provider will check you for new cancers during your treatment with REVLIMID.
- **Severe liver problems, including liver failure and death.** Your healthcare provider should do blood tests to check your liver function during your treatment with REVLIMID. 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)
 - dark or brown (tea-colored) urine
 - pain on the upper right side of your stomach area (abdomen)
 - bleeding or bruising more easily than normal
 - feeling very tired
- **Severe skin reactions and severe allergic reactions** can happen with REVLIMID and may cause death.
Call your healthcare provider right away if you develop any of the following signs or symptoms during treatment with REVLIMID:
 - 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 REVLIMID:

- swelling of your lips, mouth, tongue, or throat
- trouble breathing or swallowing
- raised red areas on your skin (hives)
- 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).** Tell your healthcare provider if you get any of these symptoms of tumor flare reaction while taking REVLIMID: tender, swollen lymph nodes; low-grade fever, pain, or rash.
- **Thyroid problems.** Your healthcare provider may check your thyroid function before you start taking REVLIMID and during treatment with REVLIMID.
- **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 REVLIMID. Talk with your healthcare provider about any concerns and possible risk factors.

The most common side effects of REVLIMID include:

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

These are not all of the possible side effects of REVLIMID. Your healthcare provider may tell you to decrease your dose, temporarily stop or permanently stop taking REVLIMID if you develop certain serious side effects during treatment with REVLIMID. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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REVLIMID REMS® PROGRAM

WHAT IS THE REVLIMID REMS® PROGRAM?

To avoid serious risks to unborn babies, REVLIMID® (lenalidomide) is only available under a restricted distribution program called the “REVLIMID Risk Evaluation and Mitigation Strategy (REMS).” Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID. In order to receive REVLIMID, patients must be enrolled in the REVLIMID REMS® program and agree to follow the requirements.

“How do I receive my first prescription?*”

MALES

-  **1. Counseling**
Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. You should be instructed not to extensively handle or open REVLIMID capsules
-  **2. Enrollment**
You and your healthcare provider will then complete and submit the REVLIMID Patient-Physician Agreement Form
-  **3. Complete Mandatory Confidential Survey**
You will not have to take a survey for your first prescription, but will have to for the following ones. Visit www.CelgeneRiskManagement.com or call **1-888-423-5436** and press 1 to take your survey
-  **4. Prescription**
Your healthcare provider will send your prescription to a certified pharmacy
-  **5. Pharmacy Call**
The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of REVLIMID before you receive your prescription. They will also coordinate delivery of REVLIMID to you
-  **6. Receive REVLIMID**
REVLIMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment

REVLIMID is only available through a restricted distribution program, REVLIMID REMS®.

For more information about REVLIMID and the REVLIMID REMS® program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**

FEMALES

-  **1. Counseling**
Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood, and about appropriate contraceptive use. You should be instructed not to extensively handle or open REVLIMID capsules
-  **2. Pregnancy Test #1**
If you can get pregnant, you must take an initial pregnancy test within 10-14 days before getting a REVLIMID prescription
-  **3. Pregnancy Test #2**
If you can get pregnant, you must take a second pregnancy test within 24 hours before getting a REVLIMID prescription
-  **4. Enrollment**
You and your healthcare provider will then complete and submit the REVLIMID Patient-Physician Agreement Form
-  **5. Complete Mandatory Confidential Survey**
You and your healthcare provider will each complete a survey. Visit www.CelgeneRiskManagement.com or call **1-888-423-5436** and press 1 to take your survey
-  **6. Prescription**
Your healthcare provider will send your prescription to a certified pharmacy
-  **7. Pharmacy Call**
The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of REVLIMID before you receive your prescription. They will also coordinate delivery of REVLIMID to you
-  **8. Receive REVLIMID**
REVLIMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment

*For each of your following prescriptions, you will need to follow a similar process. For full detailed information about the REVLIMID REMS® program requirements, please visit www.CelgeneRiskManagement.com or review the Patient Guide to REVLIMID REMS® program.

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CELGENE PATIENT SUPPORT®

A SINGLE SOURCE FOR ACCESS SUPPORT

At Celgene Patient Support®, we care about making sure you get the answers you need. That's why our Specialists are ready to help answer questions about the insurance approval process. And you may need help paying for your Celgene medicine. Celgene Patient Support® can help you and your loved ones understand the programs and services available to you.

Depending on your situation, there are programs and organizations that may help you pay for your prescribed Celgene medicine.

- Celgene Commercial Co-pay Program for eligible patients with commercial or private insurance (including healthcare exchanges)*
- Independent third-party organizations for patients with Medicare, Medicaid, or other government-sponsored insurance†
- Celgene Patient Assistance Program (PAP) for qualified patients who are uninsured or underinsured‡

ENROLLMENT IN CELGENE PATIENT SUPPORT® IS SIMPLE

We have 3 simple ways for you to enroll in Celgene Patient Support®. Choose the way that is easiest for you.



Enroll online now

You, your caregiver, or your doctor's office can enroll you in Celgene Patient Support®. Visit www.CelgenePatientSupport.com to get started.



Call your specialist

Your Specialist can enroll you over the phone, just call 1-800-931-8691, Monday – Friday, 8 AM – 8 PM ET (*translation services available*). Give us a call to get started.



E-mail or fax

Download the enrollment form. Complete the form and return it to us by e-mail at patientsupport@celgene.com or fax it to us at 1-800-822-2496. Forms are available in English or Spanish.

*Other eligibility requirements and restrictions apply. Please see full Terms and Conditions on the Celgene Patient Support® website.

†Financial and medical eligibility requirements vary by organization.

‡Patients must meet specified financial and insurance eligibility requirements to qualify for assistance. Please see Eligibility Requirements on the Celgene Patient Support® website.

ADDITIONAL SUPPORT AND RESOURCES

WHERE CAN I LEARN MORE?

Your treatment team is a great source of information. They should be able to answer most of your questions about your treatment. If you need additional information, the following resources are useful for learning more.

REVLIMID and Celgene Resources	MCL Resources	
<p>REVLIMID www.revlimid.com</p> <p>Celgene Corporation www.celgene.com</p> <p>Celgene Customer Care Center 1-888-423-5436</p> <p>Celgene Medical Services 1-888-771-0141</p> <p>Celgene Patient Support® 1-800-931-8691 www.CelgenePatientSupport.com</p>	<p>This list of independent organizations is provided as an additional resource for obtaining information related to MCL. Inclusion on this list does not indicate endorsement by Celgene Corporation of an organization or its communications.</p>	<p>American Cancer Society 1-800-227-2345 www.cancer.org</p> <p>Leukemia & Lymphoma Society 1-800-955-4572 www.lls.org</p> <p>Lymphoma Research Foundation 1-800-500-9976 www.lymphoma.org</p>

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