

MEDICATION GUIDE
REVLIMID® (rev-li-mid)
(lenalidomide)
capsules

What is the most important information I should know about REVLIMID?

- Before you begin taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS™ program (formerly known as the RevAssist® program).
- 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 (THALOMID®). We know thalidomide can 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:

- o for 4 weeks before starting REVLIMID
- o while taking REVLIMID
- o during any breaks (interruptions) in your treatment with REVLIMID
- o for 4 weeks after stopping REVLIMID

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 1-888-668-2528 for medical information.

Healthcare providers and patients should report all cases of pregnancy to:

- o FDA MedWatch at 1-800-FDA-1088, and
- o Celgene Corporation at 1-888-423-5436

REVLIMID can pass into human semen:

- o Males, including those who have had a vasectomy, must use a latex or synthetic condom during any sexual contact with a pregnant female or a female who can become pregnant while taking REVLIMID, during any breaks (interruptions) in your treatment with REVLIMID, and for 4 weeks after stopping REVLIMID.
- o 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.
- o 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 your female partner becomes pregnant, you should call your healthcare provider 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. If you are being treated for deletion 5q myelodysplastic syndromes (MDS) your blood counts should be checked weekly during the first 8 weeks of treatment with REVLIMID, and at least monthly thereafter. If you are being treated for multiple myeloma, your blood counts should be checked every 2 weeks for the first 12 weeks and then at least monthly thereafter.

- **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:

- o if you have had a blood clot in the past
- o if you have high blood pressure
- o if you smoke
- o if you have been told that you have a high level of fat in your blood (hyperlipidemia)
- o about all the medicines you take. Certain other medicines can also increase your risk for blood clots.

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

- o **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
- o **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
- o **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.

What is REVLIMID?

REVLIMID is a prescription medicine used to treat people:

- with multiple myeloma (MM) who have received at least one prior medicine, taken along with the medicine dexamethasone.
- who have a condition called myelodysplastic syndromes (MDS). REVLIMID is for the type of MDS with a chromosome problem where part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS. People with this type of

MDS may have low red blood cell counts that require treatment with blood transfusions.

- with mantle cell lymphoma (MCL) when the disease comes back or becomes worse after treatment with two prior medicines, one of which included bortezomib. Mantle cell lymphoma 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 under 18 years of age.

Who should not take REVLIMID?

- Do not take REVLIMID if you are pregnant, plan to become pregnant, or become pregnant during REVLIMID treatment. See “What is the most important information I should know about REVLIMID?”
- Do not take REVLIMID if you are allergic to lenalidomide or any of the ingredients in REVLIMID. See the end of this Medication Guide for a complete list of ingredients in REVLIMID.

What should I tell my healthcare provider before taking REVLIMID?

See “What is the most important information I should know about REVLIMID?”

Before you take REVLIMID, tell your healthcare provider if you:

- have liver problems
- have kidney problems or receive kidney dialysis treatment
- are lactose intolerant. REVLIMID contains lactose.
- have any other medical condition
- **are breastfeeding.** REVLIMID must not be used by females who are breastfeeding. 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.

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 (formerly known as the RevAssist® program).

Before prescribing REVLIMID, your healthcare provider will:

- explain the REVLIMID REMS™ program to you
- have you sign the Patient-Physician Agreement Form

- Swallow REVLIMID capsules whole with water 1 time a day. **Do not break, chew, or open your capsules.**
- Take REVLIMID at about the same time each day.
- Do not open 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 with soap and 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 or overdose, call your healthcare provider right away.

Females who can become pregnant:

- will 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 every time, for 4 weeks before, while taking, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID.

Males who take REVLIMID, even those who have had a vasectomy, must agree to use a latex or synthetic condom during sexual contact with a pregnant female or a female who can become pregnant.

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 may 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 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).** People with multiple myeloma who receive melphalan (a type of chemotherapy) and a blood stem cell transplant with the addition of REVLIMID have a higher risk of developing new cancers, including certain blood cancers (acute myelogenous leukemia or AML) and a type of lymphoma called Hodgkin lymphoma. 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.** 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

Your healthcare provider will do blood tests to check your liver function during your treatment with REVLIMID.

- **Serious skin reactions.** Serious skin reactions can happen with REVLIMID and may cause death. Call your healthcare provider right away if you have any skin reaction while taking REVLIMID.
- **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.

REVLIMID may cause serious side effects, including:

- See “What is the most important information I should know about REVLIMID?”

Common side effects of REVLIMID include:

- diarrhea
- itching
- rash
- tiredness

These are not all the possible side effects of REVLIMID.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store REVLIMID?

- Store REVLIMID at room temperature between 68°F to 77°F (20°C to 25°C).

- Return any unused REVLIMID to Celgene or your healthcare provider.

Keep REVLIMID and all medicines out of the reach of children.

General information about REVLIMID

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. **Do not** take REVLIMID for conditions for which it was not prescribed. **Do not** give REVLIMID to other people, even if they have the same symptoms you have. It may harm them and may cause birth defects.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about REVLIMID that is written for health professionals.

For more information, call 1-888-423-5436 or go to www.celgeneriskmanagement.com.

What are the ingredients in REVLIMID?

Active ingredient: lenalidomide

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 and 10 mg capsule shell contains 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.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:
Celgene Corporation
Summit, NJ 07901

Revised 2014

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