

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

Read the Medication Guide that comes with REVLIMID before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

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 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 women. REVLIMID has harmed unborn animals in animal testing.

Females must not get pregnant:

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

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

REVLIMID can pass into human semen:

- Males, including those who have had a vasectomy, must use a latex 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 4 weeks after stopping REVLIMID. (If you or your partner are allergic to latex, please consult with your healthcare provider)

- 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 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 patients. You may need a blood transfusion or certain medicines if your blood counts drop too low. If you are being treated for del 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.

A higher chance for blood clots in your veins and lungs. Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:

- shortness of breath
- chest pain
- arm or leg swelling

What is REVLIMID?

REVLIMID is a prescription medicine taken by mouth to treat certain patients who have myelodysplastic syndromes (MDS). People with MDS have bone marrow that does not produce enough mature blood cells. This causes a lack of healthy blood cells that can function properly in the body. There are different types of 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.

REVLIMID is also used with dexamethasone to treat people with multiple myeloma who have already had another treatment. Multiple myeloma is a cancer of plasma cells. Plasma cells are found in the bone marrow. Normal plasma cells produce proteins called antibodies. Some antibodies can attack and kill disease causing germs. People with multiple myeloma may have low blood cell counts and immune problems giving them a higher chance for getting infections such as pneumonia. They may also have bone pain and breaks (fractures).

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 anything in it. 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?

Tell your healthcare provider about all of your medical conditions, including if you:

- are lactose intolerant. REVLIMID contains lactose.
- **are pregnant or breastfeeding.** REVLIMID must not be used by women who are pregnant or breastfeeding. See “What is the most important information I should know about REVLIMID?” It is not known if REVLIMID passes into your breast milk and harms your baby.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription 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 RevAssist program.

Before prescribing REVLIMID, your healthcare provider will:

- explain the RevAssist program to you
- have you sign the Patient-Physician Agreement Form
- Swallow REVLIMID capsules whole with water once a day. **Do not break, chew, or open your capsules.**
- 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 or poison control center 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, 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 condom during sexual contact with a pregnant female or a female who can become pregnant. (If you or your partner is allergic to latex, please consult with your healthcare provider.)

What should I avoid while taking REVLIMID?

- **Females: Do not get pregnant and do not breastfeed while taking REVLIMID.**
Males: Do not donate sperm, See “What is the most important information I should I know about REVLIMID?”, “Who should not take REVLIMID?”, and “What should I avoid while taking REVLIMID?”.
- **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.**
- See “What is the most important information I should know about 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.** Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the breakdown products of dying cancer cells and may include the following: changes to blood chemistry, high potassium, phosphorus, uric acid, and low calcium that may lead to changes in kidney function, heart beat, seizures, and sometimes death.

- **Risk of new cancers (malignancies).** People with multiple myeloma who receive melphalan (a type of chemotherapy) or 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.

Common side effects of REVLIMID are:

- diarrhea
- itching
- rash
- tiredness

These are not all the possible side effects of REVLIMID. Tell your healthcare provider about any side effect that bothers you or that does not go away.

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, 59°F to 86°F (15°C to 30°C).

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.

This Medication Guide provides a summary of the most important information about REVLIMID. 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 healthcare professionals. You can also call 1-888-423-5436 or visit www.REVLIMID.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.

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

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