Information for patients and caregivers:

MEDICATION GUIDE

REVLIMID® (rev-li-mid)

(lenalidomide)

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®?

- **REVLIMID® is only for patients who understand and agree to all of the instructions in the RevAssist® program.**

- **REVLIMID® may cause serious side effects including:**
    1. **birth defects**
    2. **low white blood cells and platelets**
    3. **blood clots in veins and in the lungs**

1. **Possible birth defects (deformed babies) or death of an unborn baby.** Female patients who are pregnant or who plan to become pregnant must not take REVLIMID®.

   REVLIMID® is similar to the medicine thalidomide (THALOMID®). We know thalidomide causes life-threatening birth defects. REVLIMID® has not been tested in pregnant women. REVLIMID® has harmed unborn animals in animal testing.

   Female patients must not get pregnant:
   - for 4 weeks before starting REVLIMID®
   - while taking REVLIMID®
   - during dose interruptions of REVLIMID®
   - for 4 weeks after stopping REVLIMID®

   It is not known if REVLIMID® passes into semen, so:

   - Male patients, 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® and for 4 weeks after stopping REVLIMID®.

If you get pregnant while taking REVLIMID®, stop taking it right away and call your healthcare provider. Female partners of males taking REVLIMID® should call their healthcare provider right away if they get pregnant. 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

2. **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.

3. **An increased chance for blood clots in veins and in the lungs.** Call your healthcare provider or get emergency medical care right away if you get the following signs or symptoms:

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

What is REVLIMID® and what is it used for?

REVLIMID® is a medicine taken by mouth to treat certain patients who have myelodysplastic syndromes (MDS). Patients 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. Patients 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 patients 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. Plasma cells produce a protein called antibodies. Some antibodies can attack and kill disease causing germs. Patients with this type of cancer may have low blood cell counts and immune problems giving them a higher chance for getting infections such as pneumonia. The bones can be affected leading to bone pain and breaks (fractures).

REVLIMID® can only be:

- prescribed by healthcare providers who are registered in the RevAssist® program

- dispensed by a pharmacy that is registered in the RevAssist® program
- given to patients who are registered in the RevAssist® program and who agree to do everything required in the program

REVLIMID® has not been studied 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.** REVLIMID® may cause birth defects. 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 pregnant or breastfeeding.** REVLIMID® must not be used by women who are pregnant or breastfeeding.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. It is possible that 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. You must also 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

You will not be prescribed REVLIMID® if you cannot agree to or follow all of the instructions of the RevAssist® program.

You will get no more than a 28-day supply of REVLIMID® at one time. This is to make sure you follow the RevAssist® program.

- Swallow REVLIMID® capsules whole with water once a day. **Do not break, chew, or open your capsules.**

- If you miss a dose of REVLIMID®, take it as soon as you remember that day. If you miss taking your dose for the entire day, go back to taking your regular dose the next day. 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.

- You will have regular blood tests during your treatment with REVLIMID®. If you are being treated for del 5q myelodysplastic syndromes (MDS) you should have your blood tested every week during your first 8 weeks of treatment, and at least monthly after that. If you are being treated for multiple myeloma, your blood counts should be checked every two weeks for the first 12 weeks and then at least monthly after that. Your healthcare provider may adjust your dose of REVLIMID® or interrupt your treatment based on the results of your blood tests and on your general condition.

- Female patients who can get pregnant will get regular pregnancy testing.

    - get a pregnancy test weekly for 4 weeks.

- Female patients who can become pregnant must agree to use 2 separate forms of effective birth control at the same time, 4 weeks before, while taking, and for 4 weeks after stopping REVLIMID®.

- Male patients, 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.

What should I avoid while taking REVLIMID®?

- **Do not get pregnant while taking REVLIMID®** and for 4 weeks after stopping REVLIMID®. See "What is the most important information I should know about REVLIMID®?"

- **Do not breastfeed while taking REVLIMID®.** We do not know if REVLIMID® passes into your milk and harms your baby.

- **Do not share REVLIMID® with other people.** It may cause birth defects and other serious problems.

- **Do not give blood** while you take REVLIMID® 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.

- **Male patients should not donate sperm** while taking REVLIMID® and for 4 weeks after stopping REVLIMID®. If a female who is trying to become pregnant gets your sperm, 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:**
  - birth defects
  - low white blood cells and platelets
  - blood clots in veins and in the lungs

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

Other common side effects of REVLIMID® are:

- diarrhea
- itching
- rash
- tiredness

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with REVLIMID®. Ask your healthcare provider or pharmacist for more information.

How should I store REVLIMID®?

Store REVLIMID® at room temperature, 59° to 86°F (15° to 30°C).

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

General information about the safe and effective use of REVLIMID®

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. **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.

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®?

REVLIMID® (lenalidomide) capsules contain 5 mg, 10 mg, 15 mg or 25 mg of lenalidomide and are available as gelatin capsules for oral administration.

The inactive ingredients of REVLIMID® capsules are: 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 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.

Manufactured for Celgene Corporation

Summit, NJ 07901

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

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