



## Patient Information Sheet

### Lenalidomide (marketed as Revlimid)

This is a summary of the most important information about Revlimid. For details, talk to your healthcare professional.

#### What Is Revlimid?

Revlimid is a medicine taken by mouth to treat certain patients who have myelodysplastic syndrome (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 counts that require treatment with blood transfusions.

Revlimid can only be:

- prescribed by healthcare professionals 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 adhere to the program

Revlimid has not been studied in children under 18 years of age.

#### Who Should Not Use Revlimid?

Do not take Revlimid if you are:

- pregnant, plan to become pregnant or become pregnant during treatment
- allergic to Revlimid or any of the ingredients in Revlimid

#### What Are The Risks?

*The following are the major potential risks and side effects of Revlimid therapy. However, this list is not complete.*

The following are the major possible risks and side effects of Revlimid therapy:

- **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. 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 RevlimidFemale partners of males taking Revlimid should call their healthcare professional right away if they get pregnant.
- **Low white blood cells and platelets.** 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.
- **Blood clots in the veins and in the lungs.** Call your healthcare professional or get emergency medical care right away if you get the following signs or symptoms:
  - shortness of breath
  - chest pain
  - arm or leg swelling
- **Some common side effects** that may occur with Revlimid include:
  - diarrhea
  - itching
  - rash
  - tiredness

#### What Should I Tell My Healthcare Professional?

**Before you start taking Revlimid**, tell your healthcare professional if you:

- are trying to become pregnant, are already pregnant, or are breast-feeding. Revlimid must not be used by women who are pregnant or breastfeeding.
- give blood. Do not give blood while taking 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.
- donate sperm. Male patients should not donate sperm while taking Revlimid and for 4 weeks after stopping Revlimid. If a female who is

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
Druginfo@cder.fda.gov





## Patient Information Sheet

### Lenalidomide (marketed as Revlimid)

trying to become pregnant gets your sperm, her baby may be exposed to Revlimid and may be born with birth defects.

- have or had kidney problems

#### Can Other Medicines Or Food Affect Revlimid?

Tell your healthcare professional 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 with you to show your healthcare professional.

#### 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 professional 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.**
- You will have regular blood tests during treatment with Revlimid.
- If you take too much Revlimid or overdose, call your healthcare professional or poison control center right away.
- Female patients who can get pregnant will get regular pregnancy testing.
- 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.
- Do not share Revlimid with other people. It may cause birth defects and other serious problems.

Date Approved: 12/27/2005

Date Reviewed

Date Updated

