REVLIMID® (lenalidomide) is a prescription medicine, used to treat people with 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.

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.

TAKE AN ACTIVE ROLE
A guide to starting treatment with REVLIMID for deletion 5q MDS

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

Please see full accompanying Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-5.
Important Safety Information

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. 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 who are pregnant or who plan to become pregnant must not take REVLIMID.
- 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 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.
  - 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 use two different forms of effective contraception at the same time, 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.

If you have had a blood clot in the past, you should not take REVLIMID. If you have had a blood clot in the past, you should not take REVLIMID. If you have had a blood clot in the past, you should not take REVLIMID.

Who should not take REVLIMID?

- Do not take REVLIMID if you are allergic to lenalidomide or any of the ingredients in REVLIMID.
- Do not take REVLIMID if you are pregnant, plan to become pregnant, or become pregnant while taking REVLIMID during any breaks (interruptions) in your treatment with REVLIMID.
- Do not take REVLIMID if you have had a blood clot in the past.
- Do not take REVLIMID if you have high blood pressure, smoke, or if you have been told you have a high level of fat in your blood (hyperlipidemia).
- Do not take REVLIMID if you have an active bleeding problem or if you have had a blood clot in the past.
- Do not take REVLIMID if you are taking or plan to take a blood thinner or another type of medicine that could lower your blood clotting ability.
- Do not take REVLIMID if you are taking or plan to take a blood thinner or another type of medicine that could lower your blood clotting ability.
- Do not take REVLIMID if you are taking or plan to take a blood thinner or another type of medicine that could lower your blood clotting ability.

REVLIMID® is only available through a restricted distribution program, REVLIMID REMS®.
Important Safety Information (cont’d)

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. 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. 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 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 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

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 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?”

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

Important Safety Information (cont’d)

- 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). 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), and myelodysplastic syndrome (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 including severe allergic reactions can happen with REVLIMID and may cause death. Call your healthcare provider right away if you develop any of these signs or symptoms of a severe allergic reaction or severe skin reaction during treatment with REVLIMID:
  - swelling of your face, eyes, lips, tongue, throat
  - trouble swallowing
  - trouble breathing
  - rash with fever and or swollen glands
- 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
- constipation
- itching
- rash
- tiredness
- nausea
- fever
- swelling of the limbs and skin
- cough

These are not all 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

Please see full accompanying Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-5.
## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Important Safety Information</td>
<td>2-5</td>
</tr>
<tr>
<td>Understanding Myelodysplastic Syndromes (MDS)</td>
<td>8-9</td>
</tr>
<tr>
<td>What Is Deletion 5Q MDS?</td>
<td>10</td>
</tr>
<tr>
<td>What Is REVLIMID?</td>
<td>11</td>
</tr>
<tr>
<td>Important Information About REVLIMID REMS®</td>
<td>12-15</td>
</tr>
<tr>
<td>How to Take REVLIMID REMS®</td>
<td>16-17</td>
</tr>
<tr>
<td>Having Regular Blood Tests</td>
<td>18-19</td>
</tr>
<tr>
<td>What Are the Serious Side Effects of REVLIMID?</td>
<td>20-21</td>
</tr>
<tr>
<td>What Are the Possible Side Effects of REVLIMID?</td>
<td>22-25</td>
</tr>
<tr>
<td>Taking an Active Role</td>
<td>26-29</td>
</tr>
<tr>
<td>Taking Care of Yourself</td>
<td>30-31</td>
</tr>
<tr>
<td>Glossary of Terms</td>
<td>32-33</td>
</tr>
<tr>
<td>Medication Guide</td>
<td>34-40</td>
</tr>
<tr>
<td>Helpful Resources</td>
<td>Back Cover</td>
</tr>
</tbody>
</table>
UNDERSTANDING MYELODYSPLASTIC SYNDROMES (MDS)

MDS is a cancer that affects the blood and bone marrow. Bone marrow is the soft, sponge-like tissue in the center of most bones that makes your blood cells.

When you have MDS, your bone marrow does not totally stop working. Patients with MDS have bone marrow that does not make enough mature blood cells. This means there are fewer healthy blood cells working in the body, which can affect the way you feel.

People with MDS typically have low blood cell counts, which means they have low levels of red blood cells (RBCs) (anemia) (an•EE•mee•uh), white blood cells (WBCs) (neutropenia) (noo•trop•EE•nee•uh), and/or platelets (PLATE•lets) (thrombocytopenia) (THROM•boh•sy•toh•PEE•nee•uh) in the bloodstream.

NORMAL BLOOD CELL DEVELOPMENT

Some of the types of cells your bone marrow makes are:

- **Stem cells**: These divide again and again to make more stem cells. They also make blasts.
- **Blasts**: These young cells mature into RBCs, WBCs, or platelets.
- **Red blood cells**: RBCs help carry oxygen to your muscles, brain, heart, and other organs. Without enough RBCs, you might get tired and/or out of breath more easily.
- **White blood cells**: WBCs help your body fight infection.
- **Platelets**: Platelets help form blood clots and stop bleeding.

**Bone marrow**

**Bone**
WHAT IS DELETION 5Q MDS?

There are different types of MDS. REVLIMID® (lenalidomide) treats the type of MDS in which part of chromosome 5 is missing. This type of MDS is known as deletion 5q (del 5q) MDS. Patients with this type of MDS have low red blood cell (RBC) counts that require treatment with blood transfusions. Your doctor will be able to tell if you have del 5q MDS by testing some of your bone marrow cells.

WHAT IS REVLIMID® (lenalidomide)?

- REVLIMID is a prescription medicine, used to treat people with 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
- 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

How was REVLIMID studied?

- REVLIMID was evaluated in one clinical study that enrolled a total of 148 patients with low or intermediate risk MDS
- These patients who had MDS del 5q required red blood cell transfusions
- The study evaluated patients taking REVLIMID to determine if they would no longer require red blood cell transfusions (transfusion independence). Red blood cell transfusion independence was defined as the absence of any RBC transfusions during a consecutive 56 days during treatment

What were the results of REVLIMID?

- The study showed that 99 of 148 patients (67%) responded to treatment, reaching transfusion independence for 56 consecutive days (8 weeks) during the study period
- 90% of patients who reached RBC transfusion independence did so by the end of the third month in the study
- 80% of patients needed to have their medication reduced or interrupted at least once due to a serious side effect
- A second dose interruption was needed in 34% of patients

REVLIMID® may cause serious side effects including:

- Birth defects
- Low white blood cell and platelet counts
- Blood clots in your arteries, veins, and lungs
- Increased risk of death in people who have chronic lymphocytic leukemia (CLL)
- Risk of new cancers (malignancies)
- Severe liver problems, including liver failure and death
- Severe allergic reactions and severe skin reactions
- Tumor lysis syndrome (TLS)
- Worsening of your tumor (tumor flare reaction)
- Thyroid problems
- Risk of Early Death in MCL

These are not all the possible side effects of REVLIMID. For additional information regarding side effects, see the side effects section of this brochure or speak with your doctor.

You may report side effects to FDA at 1-800-FDA-1088.
IMPORTANT INFORMATION ABOUT REVLIMID REMS®

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

IMPORTANT INFORMATION ABOUT REVLIMID REMS® (CONT’D)

- 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.
- If a female becomes pregnant with your sperm, you should call your HCP right away. The baby may be exposed to REVLIMID and may be born with birth defects.
- 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.
- Only prescribers certified with REVLIMID REMS® can prescribe REVLIMID.
- Only pharmacies certified with REVLIMID REMS® can dispense REVLIMID.
- In order to receive REVLIMID, patients must enroll in REVLIMID REMS® and agree to comply with the requirements of the REVLIMID REMS® program.
- To learn more about REVLIMID and the REVLIMID REMS® program, call Celgene Customer Care Center at 1-888-423-5436 or visit www.celgeneriskmanagement.com.

Please see full accompanying Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-5.
### REVLIMID REMS® Program

**How to receive your first prescription for REVLIMID® (lenalidomide)**

<table>
<thead>
<tr>
<th><strong>MALES</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Counseling</strong></td>
</tr>
<tr>
<td>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® (lenalidomide) capsules</td>
</tr>
<tr>
<td><strong>Enrollment</strong></td>
</tr>
<tr>
<td>You and your healthcare provider will then complete and submit the REVLIMID® (lenalidomide) Patient-Physician Agreement Form</td>
</tr>
<tr>
<td><strong>Complete Mandatory Confidential Survey</strong></td>
</tr>
<tr>
<td>You will not have to take a survey for your first prescription, but will have to for the following ones. Visit <a href="http://www.CelgeneRiskManagement.com">www.CelgeneRiskManagement.com</a> or call 1-888-423-5436 and press 1 to take your survey</td>
</tr>
<tr>
<td><strong>Prescription</strong></td>
</tr>
<tr>
<td>Your healthcare provider will send your prescription to a certified pharmacy</td>
</tr>
<tr>
<td><strong>Pharmacy Call</strong></td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td><strong>Receive REVLIMID</strong></td>
</tr>
<tr>
<td>REVLIMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment</td>
</tr>
</tbody>
</table>

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.

### FEMALES

| **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® (lenalidomide) capsules |
| **Pregnancy Test #1** |
| If you can get pregnant, you must take an initial pregnancy test within 10-14 days before getting a REVLIMID prescription |
| **Pregnancy Test #2** |
| If you can get pregnant, you must take a second pregnancy test within 24 hours before getting a REVLIMID prescription |
| **Enrollment** |
| You and your doctor will then complete and submit the Patient-Physician Agreement Form |
| **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 |
| **Prescription** |
| Your healthcare provider will send your prescription to a certified pharmacy |
| **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 |
| **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, pregnancy tests will be required depending on your ability to get pregnant. For full detailed information about the REVLIMID REMS® program requirements, please visit www.CelgeneRiskManagement.com or review the Patient Guide to REVLIMID REMS® program.

**REVLIMID® is only available through a restricted distribution program, REVLIMID REMS®.**
HOW TO TAKE REVLIMID

The recommended starting dose for REVLIMID is 10 mg every day, but your doctor will tell you which dose is right for you.

My dose of REVLIMID is ____________________________

I will take REVLIMID at about the same time each day.

REVLIMID® (lenalidomide) is a prescription medicine, used to treat people with 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.

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.

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 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 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.

A HELPFUL TIP:

This toolkit contains a medication tracker where you can list all the medications, vitamins, and supplements you are taking.

CALENDAR FOR TRACKING YOUR MEDICATIONS

<table>
<thead>
<tr>
<th>SUNDAY</th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REVLIMID® is only available through a restricted distribution program, REVLIMID REMS®.
HAVING REGULAR BLOOD TESTS

To check that your blood counts are at safe levels while you are taking REVLIMID, your doctor or nurse will require regular blood tests, called complete blood counts (CBCs). If your blood counts are low, a dose reduction or a temporary dose interruption of your therapy may be required. Dose reduction or dose interruption occurs in most patients with del 5q MDS taking REVLIMID.

Depending on the results of your blood tests, your doctor or nurse may add other medications to your treatment or give you a blood transfusion. In some cases, patients have had to stop taking REVLIMID due to side effects.

**CBC TEST MEASURES THE FOLLOWING COMPONENTS AND FEATURES OF YOUR BLOOD:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>White blood cells (WBCs)</td>
<td>help fight infection</td>
</tr>
<tr>
<td>Red blood cells (RBCs)</td>
<td>carry oxygen to the tissues and organs of the body</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>a protein molecule in RBCs that carries oxygen to the tissues and organs of the body. If hemoglobin levels are low, you may have anemia</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>the percentage of red blood cells in your body compared with the total amount of blood in your body</td>
</tr>
<tr>
<td>Platelets</td>
<td>help form blood clots and stop bleeding</td>
</tr>
<tr>
<td>Mean corpuscular volume (MCV)</td>
<td>a measure of the average size of RBCs. MCV is high when RBCs are larger than normal and low when they are smaller than normal</td>
</tr>
</tbody>
</table>

**RISK INFORMATION ABOUT REVLIMID AND BLOOD**

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 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

**A HELPFUL TIP:**

This toolkit contains a helpful tracker so you can write down your lab results and share this information during your next doctor’s appointment.
WHAT ARE THE SERIOUS SIDE EFFECTS OF REVLIMID?

- REVLIMID may cause serious side effects, including:
  - Birth defects or death of an unborn baby
  - Low white blood cell and platelet counts
  - Blood clots in your arteries, veins, and lungs

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) 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.

Neutropenia

Neutropenia means having low levels of neutrophils, a type of WBC. Neutropenia reduces your ability to fight infections and has been seen in almost 60% of patients with del 5q MDS taking REVLIMID. Signs of neutropenia that you should talk to your doctor or nurse about right away include:

- A fever (temperature of 100.5°F or higher)
- Chills or sweating
- Sore throat, sores in the mouth, or a toothache
- Abdominal pain
- Pain in the perirectal (anal) area
- Pain or burning when urinating, or frequent urination
- Diarrhea or sores around the anus
- A cough or shortness of breath

Thrombocytopenia

Thrombocytopenia means having a low number of platelets. As a result, your blood may not clot the way it should. Thrombocytopenia has been seen in more than 62% of patients with del 5q MDS taking REVLIMID. Signs of thrombocytopenia that you should tell your doctor or nurse about right away include:

- Increased bruising (bruising easily, bruises that won’t go away)
- Unusual bleeding (bleeding from your gums, bleeding that won’t stop quickly)

Blood clots

Blood clots in the arteries, veins, and lungs happen more often in people who take REVLIMID

- Before taking REVLIMID tell your healthcare provider:
  - if you have had a blood clot in the past
  - if you have high blood pressure
  - if you smoke
  - if you have been told you have a high level of fat in your blood (hyperlipidemia)
  - about all 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 signs or symptoms during treatment with REVLIMID:

<table>
<thead>
<tr>
<th>POSSIBLE MEDICAL CONDITION</th>
<th>SIGNS OR SYMPTOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood clot in lung, arm, or leg</td>
<td>• Shortness of breath</td>
</tr>
<tr>
<td></td>
<td>• Chest pain</td>
</tr>
<tr>
<td>Heart attack</td>
<td>• Chest pain that may spread to arms, neck, jaw, back, or stomach area (abdomen)</td>
</tr>
<tr>
<td></td>
<td>• Feeling sweaty</td>
</tr>
<tr>
<td></td>
<td>• Shortness of breath</td>
</tr>
<tr>
<td></td>
<td>• Feeling sick or vomiting</td>
</tr>
<tr>
<td>Stroke</td>
<td>• Sudden numbness or weakness, especially on one side of the body</td>
</tr>
<tr>
<td></td>
<td>• Severe headache or confusion</td>
</tr>
<tr>
<td></td>
<td>• Problems with vision, speech, or balance</td>
</tr>
</tbody>
</table>

A HELPFUL TIP:

Expect to have your blood tested often especially during the first several months of treatment, then at least once a month thereafter.

It’s important that your doctor or nurse monitor your blood counts while you are on REVLIMID. To report suspected adverse reactions, please contact the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.
WHAT ARE THE POSSIBLE SIDE EFFECTS OF REVLIMID?

In a clinical study of 148 patients with del 5q MDS who took REVLIMID, the following side effects were reported:

**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)**

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), and myelodysplastic syndrome (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 including severe allergic reactions**

Severe allergic reactions and severe skin reactions can happen with REVLIMID and may cause death. Call your healthcare provider right away if you develop any of these signs or symptoms of a severe allergic reaction or severe skin reaction during treatment with REVLIMID:

- swelling of your face, eyes, lips, tongue, throat
- trouble swallowing
- trouble breathing
- skin rash, hives, or peeling of your skin
- blisters
- rash with fever and or swollen glands

**Allergic reactions**

Tell your healthcare provider if you are lactose intolerant as REVLIMID contains lactose.

**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.

**Rash and itching**

Some patients taking REVLIMID reported rash (36%) and itching (42%).

---

REVLIMID® is only available through a restricted distribution program, REVLIMID REMS®.
WHAT ARE THE POSSIBLE SIDE EFFECTS OF REVLIMID? (CONT’D)

Breathing problems
Some patients with del 5q MDS reported difficulty breathing (17%) and cough (20%) while taking REVLIMID. If you have problems breathing, experience shortness of breath, or notice any respiratory changes, tell your doctor or nurse immediately.

Swelling in the arms and legs
Some patients taking REVLIMID have reported swelling (edema) of the limbs (20%), with or without pain. This symptom usually occurs in the feet and ankles but may include the calves or thighs. If you have swelling of the limbs, tell your doctor or nurse.

Diarrhea
Nearly half of the patients (49%) reported diarrhea. Some patients taking REVLIMID had watery stools that lasted more than a few days. It is helpful to increase the amount of liquids you drink to keep hydrated.

Because diarrhea can sometimes be serious, tell your doctor or nurse about any diarrhea right away so it can be treated.

Constipation
Some patients taking REVLIMID reported constipation (24%). If needed, your doctor or nurse may recommend a mild laxative. Be sure to talk to your doctor or nurse before using a laxative or stool softener.

Nausea, vomiting, and abdominal pain
Some patients taking REVLIMID reported nausea (24%), vomiting (10%), or upper abdominal pain (8%). Nausea is an unpleasant wavelike feeling in the stomach and back of the throat that can lead to vomiting. If you have any nausea, tell your doctor or nurse.

Fatigue and weakness
More than 30% of patients with del 5q MDS taking REVLIMID reported feeling tired. Feeling tired can range from a mild lack of energy to feeling completely exhausted. In some patients, fatigue and weakness can last a long time.

Dizziness and headaches
During treatment with REVLIMID, some patients reported sudden dizziness (20%) or headaches (20%). Dizziness may occur after standing up from a reclining or sitting position. If you have dizziness or headaches, tell your doctor or nurse.

Pain in the back, arms, legs, and muscles
During treatment with REVLIMID, some patients reported pain in the limbs (11%), joint pain (22%), back pain (21%), and muscle cramps (18%). If you have any signs of pain that began after starting treatment, or pain that continues, tell your doctor or nurse. These are not all the possible side effects with REVLIMID. Tell your doctor or nurse about any side effect that bothers you or that does not go away. Ask your doctor, nurse, or pharmacist for more information.

IMPORTANT REMINDER ABOUT SIDE EFFECTS:
Tell your doctor or nurse right away if you experience any side effects while taking REVLIMID.

REVLIMID® is only available through a restricted distribution program, REVLIMID REMS®.
TAKING AN ACTIVE ROLE

Here are some ideas to help you be a more active partner in your treatment with REVLIMID.

Know who is on your treatment team:

<table>
<thead>
<tr>
<th>SPECIALTY</th>
<th>NAME AND CONTACT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncologist/hematologist</td>
<td></td>
</tr>
<tr>
<td>Oncology nurse/nurse practitioner</td>
<td></td>
</tr>
<tr>
<td>Physician assistant</td>
<td></td>
</tr>
<tr>
<td>Social worker</td>
<td></td>
</tr>
<tr>
<td>Psychologist or psychiatrist</td>
<td></td>
</tr>
<tr>
<td>Registered dietitian</td>
<td></td>
</tr>
<tr>
<td>Specialty pharmacist</td>
<td></td>
</tr>
<tr>
<td>Insurance case manager</td>
<td></td>
</tr>
<tr>
<td>Spiritual leader</td>
<td></td>
</tr>
</tbody>
</table>

Remember that you are not alone during your treatment. Your doctor and nurse are here to support you along the way.

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

Be prepared with questions to ask your healthcare team:

- How should I take my medicine and how often should I take it?
- What are the possible side effects of this medicine?
- What type of tests will I need to have during my treatment?
- Where can I find more information about support services available to my family and me?

A HELPFUL TIP:

A GUIDE TO HELP YOU STAY ORGANIZED is available in this toolkit and has more questions that you can ask your doctor or nurse about treatment with REVLIMID.
TAKING AN ACTIVE ROLE (CONT’D)

Use active listening to have better conversations with your support team.

Here are some tips to keep in mind:

Pay close attention
So the speaker knows that you are actively engaged in the conversation.

Repeat or rephrase
What was just said in your own words, to be sure that you fully understand the information that is being discussed.

Summarize
Some important key points of the conversation. This will help you retain information after your discussion.

Be ready to take action when it comes to:

Awareness of side effects
Learn about possible signs and symptoms (described in this booklet) of the most common side effects.
• Call your doctor or nurse right away if you experience side effects

Understanding blood tests
Knowing the results of your blood tests may be helpful to you during your treatment with REVLIMID.
• The results give you and your doctor important information about your blood, such as knowing if your blood counts are too low
• If you miss a blood test, reschedule it right away

Sharing information
Be sure to let your doctor or nurse know about all the other medicine(s) you are taking before you start treatment with REVLIMID.
• This includes prescription medicines, over-the-counter and herbal medicines, vitamins, and dietary supplements

Asking for help
Do not be afraid to reach out to a family member, friends, or your doctor for any additional support or help that you may need.

A HELPFUL TIP:
On the back cover of this booklet is the Helpful Resources section, where you can find a list of support organizations.

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

Please see full accompanying Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-5.
TAKING CARE OF YOURSELF

The stress caused by having MDS or being on treatment can be challenging. That is why it is important to take care of your body and mind during treatment with REVLIMID.

If you feel stressed or overwhelmed, take a moment to quiet your thoughts.
- It may be helpful to organize important information and resources you will need for the next step of your treatment plan. Pacing yourself can help you accomplish this task.

It is important to eat a healthy, balanced diet:
- A registered dietitian can help you plan your meals and come up with new and exciting recipes.

Your family and friends can provide valuable support during your treatment. Often people may want to help, but just do not know how.
- It is important to let people know exactly how they can offer their support by giving examples of how they can help. Ask them to drive you to your doctor appointments or go shopping for you.
- Making an effort to continue with social activities, such as staying in touch with your friends and reaching out to the local community, religious groups, or co-workers is a great place to start.

Be sure to talk about both positive and negative feelings with others.
- Share your concerns with members of your support team.
- The journal provided in this kit can help you express your thoughts and feelings.

If you are feeling stressed about your disease or treatment, it is important to let those feelings out. Talk to a family member, friend, social worker, or any other member of your support team.
- Social workers, psychologists, and psychiatrists can all help you deal with stress and feel more relaxed during treatment and beyond.

Keeping a positive outlook can help you face the challenges ahead. MDS is just one part of your life. Remember to make time for the things you enjoy the most. Speaking with other patients or getting involved with support groups is a great place to start.
- A list of support organizations can be found on the back cover of this brochure.

It is important to keep copies of your medical records with you just in case you need to refer to them during your treatment.
- Ask a family member or friend to accompany you to your doctor appointments, to help you keep important data organized.

A HELPFUL TIP:
Keeping a personal journal updated with your thoughts and feelings is a great source of inspiration. We have included a notebook in this toolkit to help get you started.

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

Please see full accompanying Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-5.
## GLOSSARY OF TERMS

<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>A condition in which the number of red blood cells (RBCs) is below normal</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>The soft, sponge-like tissue in the center of bones that makes RBCs, white blood cells (WBCs), and platelets</td>
</tr>
<tr>
<td>Chromosome</td>
<td>A structure that contains your genetic information, or DNA</td>
</tr>
<tr>
<td>Complete blood counts</td>
<td>Laboratory tests that count the total number of cells in a blood sample</td>
</tr>
<tr>
<td>Cytopenia</td>
<td>Reduction in the number of blood cells</td>
</tr>
<tr>
<td>Deletion 5q (del 5q)</td>
<td>A chromosomal abnormality in which part of chromosome 5 is missing</td>
</tr>
<tr>
<td>Dose interruption</td>
<td>A period of time when you are not taking REVLIMID</td>
</tr>
<tr>
<td>Dose reduction</td>
<td>A lowering of your dose of REVLIMID</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Referring to the stomach and intestines</td>
</tr>
<tr>
<td>Myelodysplastic syndromes</td>
<td>Derived from myelo, which means marrow, and dysplasia, which means abnormal growth. MDS is a group of diseases in which the bone marrow does not make enough healthy blood cells</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>A condition in which the number of neutrophils (the most numerous type of WBC, which helps fight infection) is below normal in the blood</td>
</tr>
<tr>
<td>Platelets</td>
<td>Blood cells that are essential for blood clotting</td>
</tr>
<tr>
<td>Red blood cells</td>
<td>The cells that carry oxygen to the body's tissues</td>
</tr>
<tr>
<td>Stem cell</td>
<td>A cell that is produced in the bone marrow and matures into a healthy cell, such as an RBC, WBC, or platelet</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>A condition in which the number of platelets, or thrombocytes, is below normal, resulting in the tendency to bruise and bleed more easily</td>
</tr>
<tr>
<td>Transfusions</td>
<td>Procedures that add parts of blood or whole blood into the bloodstream</td>
</tr>
<tr>
<td>White blood cells</td>
<td>The cells that help the body fight infection</td>
</tr>
</tbody>
</table>

REVLIMID® is only available through a restricted distribution program, REVLIMID REMS®.
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. 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. We know thalidomide can cause severe life-threatening birth defects. REVLIMID has not been tested in pregnant females.

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:

- 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 two acceptable forms of 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 acceptable 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.

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

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 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. 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)
  - About all the medicines you take. Certain other medicines can also increase your risk for blood clots
MEDICATION GUIDE (CONT’D)

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

What is REVLIMID?
REVLIMID® is a prescription medicine, used to treat people with:

• multiple myeloma (MM)
  - in combination with the medicine dexamethasone, or
  - as maintenance treatment after autologous hematopoietic stem cell transplantation (a type of stem cell transplant that uses your own stem cells)
• 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.
• 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.

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 end of this Medication Guide for a complete list of ingredients in REVLIMID.

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

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 or break 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.
  - 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.

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.
MEDICATION GUIDE (CONT’D)

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 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), and myelodysplastic syndrome (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 including severe allergic reactions** can happen with REVLIMID and may cause death. Call your healthcare provider right away if you develop any of these signs or symptoms of a severe allergic reaction or severe skin reaction during treatment with REVLIMID:
  - swelling of your face, eyes, lips, tongue, throat
  - trouble swallowing
  - trouble breathing
  - skin rash, hives, or peeling of your skin
  - blisters
  - rash with fever and or swollen glands

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

• **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.

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.

- **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
- fever
- itching
- swelling of the limbs and skin
- cough

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 the 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.
MEDICATION GUIDE (CONT’D)

General information about the safe and effective use of 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.

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 shell contains 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.

Manufactured for: Celgene Corporation, Summit, NJ 07901

REVLIMID® and REVLIMID REMS® are registered trademarks of Celgene Corporation.


All rights reserved. REVPyMG.022 09/2017

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

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

Revised: September 2017
HELPFUL RESOURCES

CELENE RESOURCES

<table>
<thead>
<tr>
<th>Celgene Corporation</th>
<th>Celgene Customer Care Center</th>
<th>Celgene Medical Information</th>
<th>Patient Information for REVLIMID</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.celgene.com">www.celgene.com</a></td>
<td>1-888-423-5436</td>
<td>1-888-771-0141</td>
<td><a href="http://www.REVLIMID.com">www.REVLIMID.com</a> 1-800-931-8691</td>
</tr>
</tbody>
</table>

**Celgene Patient Support®** www.CelgenePatientSupport.com 1-800-931-8691

At Celgene Patient Support®, we care about making sure you get the help you need to start your treatment. Our Specialists are ready to help you and your family with:

- Understanding your insurance plan
- Learning about financial assistance that may help you pay for REVLIMID
- Obtaining information about organizations that may assist you with travel costs to and from your doctor’s office

ADDITIONAL RESOURCES

It’s important to know that there are independent third-party resources available to help you be more informed and involved during your treatment. In this section, you can discover organizations* that may be able to offer you and your loved one support during your treatment journey. Celgene Patient Support® can also provide information about other independent third-party organizations based on your diagnosis and support needs.

<table>
<thead>
<tr>
<th>American Cancer Society</th>
<th>Aplastic Anemia &amp; MDS International Foundation Inc.</th>
<th>Leukemia &amp; Lymphoma Society</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-800-ACS-2345</td>
<td>1-800-747-2820</td>
<td>1-800-955-4572</td>
</tr>
<tr>
<td>(1-800-227-2345)</td>
<td><a href="http://www.aamds.org">www.aamds.org</a></td>
<td><a href="http://www.lls.org">www.lls.org</a></td>
</tr>
<tr>
<td><a href="http://www.cancer.org">www.cancer.org</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leukemia Research Foundation</th>
<th>Myelodysplastic Syndromes Foundation</th>
<th>National Cancer Institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-888-558-5385</td>
<td>1-800-MDS-0839</td>
<td>1-800-4-CANCER</td>
</tr>
<tr>
<td><a href="http://www.leukemia-research.org">www.leukemia-research.org</a></td>
<td>(1-800-637-0839)</td>
<td>(1-800-422-6237)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.mds-foundation.org">www.mds-foundation.org</a></td>
<td><a href="http://www.cancer.gov">www.cancer.gov</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National Alliance for Caregiving (NAC)</th>
<th>ClinicalTrials.gov</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.caregiving.org">www.caregiving.org</a></td>
<td><a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a></td>
</tr>
</tbody>
</table>

*Celgene does not endorse any of these organizations or their communications.

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

Please see full accompanying Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-5.

REVLIMID®, REVLIMID REMS® and Celgene Patient Support® are registered trademarks of Celgene Corporation.