REVLIMID® (lenalidomide) is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require 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 under 18 years of age.

Getting Started With REVLIMID

Deletion 5q myelodysplastic syndromes

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

For additional information about REVLIMID® (lenalidomide) and REVLIMID REMS®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com.

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

Getting Started With REVLIMID

Deletion 5q myelodysplastic syndromes

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

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Getting Started With REVLIMID

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For additional information about REVLIMID® (lenalidomide) and REVLIMID REMS®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com.

Please see accompanying full Prescribing Information, including Boxed WARNINGS and Medication Guide, in pocket and Important Safety Information on pages 2-5.
WARNING: Risk to unborn babies, low blood counts, and blood clots

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.

In females of childbearing potential, obtain 2 negative pregnancy tests before starting REVLIMID treatment.

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

If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider. It is not known if REVLIMID passes into your breast milk and harms your baby.

Males

• REVLIMID can pass into human semen. Males, including those who have had a vasectomy, must use a barrier device during any sexual contact with a pregnant female or a female who can become pregnant. Males must do this 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.

Females and Males

• 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.

Important Safety Information (continued)

REVLIMID® (lenalidomide) is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndrome (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require 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 under 18 years of age.

Important Safety Information
Other serious side effects

- Blood clots
- Risk is even higher for people with multiple myeloma taking REVLIMID with dexamethasone
- Heart attacks and stroke also happen more often in people taking 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, have high blood pressure, you smoke, you have been told you have high level of fat in your blood (hyperlipidemia), and 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 these signs or symptoms during treatment with REVLIMID:

- Blood clot in lung, arm or leg: shortness of breath, chest pain, or arm or leg swelling.
- Heart attack: chest pain that may spread to arms, neck, jaw, back or stomach area, feeling sweaty, shortness of breath, feeling sick or vomiting.
- Stroke: sudden numbness or weakness, especially on one side of the body, severe headache or confusion, or problems with vision, speech or balance.

Other important information 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 MM who receive REVLIMID and melphalan may have a higher risk of developing new cancers, including certain blood cancers (acute myelogenous leukemia or AML and myelodysplastic syndrome or MDS) 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: 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, bleeding or bruising more easily than normal and feeling very tired. Your healthcare provider will do blood tests to check your liver function during treatment with REVLIMID.

- Serious allergic reactions and serious 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 serious allergic reaction or serious skin reaction: swelling of your face, eyes, lips, tongue, throat; trouble swallowing or breathing, skin rash, hives or peeling of your skin and blisters.

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

- 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. This may lead to changes in kidney function, heartbeat, seizures, and sometimes death.

- Worsening of your tumor (tumor flare reaction). Tell your healthcare provider if you get any of these symptoms while taking REVLIMID: tender swollen lymph nodes, low-grade fever, pain or rash.

Common side effects

- Common side effects of REVLIMID are diarrhea, constipation, itching, rash, tiredness, swelling of the limbs and skin, nausea, fever and cough.

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

Drug interactions

- REVLIMID with or without dexamethasone may affect how certain other medicines work. Especially tell your healthcare provider if you take or use warfarin (a blood thinner) or digoxin (a medicine used to treat heart problems including abnormal heart beats). Your healthcare provider may want to test your blood more often.

- Medicines that may cause blood clots, such as those that help make more red blood cells or those that contain estrogen, should be used cautiously in patients with MM who are taking REVLIMID with dexamethasone.

Other important information about REVLIMID

Swallow REVLIMID capsules whole with water once a day. Do not open, break or chew 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 have kidney problems or are on dialysis, be sure to talk with your doctor. He or she may need to adjust your dose of REVLIMID.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, in pocket.
Important Information about REVLIMID REMS®

• To avoid serious risks to unborn babies, REVLIMID is only available through a restricted distribution program called REVLIMID REMS® program (formerly known as the RevAssist® program).

• Females: Do not get pregnant or breastfeed. REVLIMID must not be used by females who are pregnant or breastfeeding. It is not known if REVLIMID passes into your breast milk and harms your baby

• Females who can become pregnant:
  — Will have 2 negative pregnancy tests done by your healthcare provider. The first test should be done 10 to 14 days before your healthcare provider prescribes REVLIMID, and the second test should be done within 24 hours before REVLIMID is prescribed
  — 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
  — If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider

• REVLIMID can pass into human semen. Males, including those who have had a vasectomy, must use a latex or synthetic condom every time during any sexual contact with a pregnant female or a female that can become pregnant. Males must do this 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)

• Males: Do not donate sperm while taking REVLIMID, during any breaks (interruptions) in your treatment with REVLIMID, 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

• 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

WARNING: Risk to unborn babies, low blood counts, and blood clots

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.

In females of childbearing potential, obtain 2 negative pregnancy tests before starting REVLIMID treatment.

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

If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider.

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

REVLIMID causes a higher chance for blood clots in your veins (deep vein thrombosis), lungs (pulmonary embolism), and arteries (heart attack or stroke).
Females who can become pregnant must agree to use 2 different forms of effective birth control at the same time every time for 4 weeks before starting, while taking, during any breaks (interruptions) in treatment with, and for 4 weeks after stopping REVLIMID® (lenalidomide).

- Once treatment has started and during dose interruptions, pregnancy testing for females of childbearing potential should occur weekly during the first 4 weeks of use, then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
- If you become pregnant while taking REVLIMID, stop taking it right away and call your healthcare provider
- Lenalidomide is contraindicated in pregnant women and women capable of becoming pregnant. Females of childbearing potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- REVLIMID can pass into human semen. 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 that can become pregnant. Males must do this 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)

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

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, in pocket and Important Safety Information on pages 2-5.
What is deletion 5q MDS?

Patients with myelodysplastic syndromes (MDS) have bone marrow that does not make enough mature blood cells. This means there are fewer healthy blood cells working in the body. There are different types of MDS. REVLIMID® (lenalidomide) treats the type of MDS where part of chromosome 5 is missing. This type of MDS is known as deletion 5q (del 5q) MDS. Patients with this type of MDS may 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?

REVLIMID is a prescription medicine taken by mouth. REVLIMID is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require blood transfusions.

What is the most important information about REVLIMID?

• Before you begin taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS® 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. If you are a woman who can become pregnant, you should have 2 pregnancy tests that show you are not pregnant before starting REVLIMID.
  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
  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

A full Glossary may be found on page 29.
What is the most important information about REVLIMID® (lenalidomide)? (continued)

REVLIMID® can pass into human semen:

- 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. 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. Men, if your female partner becomes pregnant, you should call your healthcare provider right away.

- 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.

Low white blood cells (neutropenia) and low platelets (thrombocytopenia). REVLIMID® (lenalidomide) 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 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.

Risk is even higher for people with multiple myeloma taking REVLIMID with dexamethasone. Heart attacks and stroke also happen more often in people taking 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, have high blood pressure, you smoke, you have been told you have high level of fat in your blood (hyperlipidemia), and 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:

- Blood clot in lung, arm or leg: shortness of breath, chest pain, or arm or leg swelling. Heart attack: chest pain that may spread to arms, neck, jaw, back or stomach area, feeling sweaty, shortness of breath, feeling sick or vomiting. Stroke: sudden numbness or weakness, especially on one side of the body, severe headache or confusion, or problems with vision, speech or balance.

Your treatment with REVLIMID

Some side effects may be serious and may require your doctor or nurse to interrupt (dose interruption), lower your dose (dose reduction), or stop REVLIMID treatment.

Only your doctor can decide what dose of REVLIMID is right for you. If you notice any changes in the way you feel or changes in your body that are troubling, it is very important that you tell your doctor or nurse right away.

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 temporary dose interruption of your therapy may be required. Dose reduction or dose interruption occurs in many patients with del 5q MDS taking REVLIMID. Depending on the results of your blood tests, your doctor or nurse may add other medicines to your treatment or give you a blood transfusion. In some cases, patients have had to stop taking REVLIMID due to side effects.

- Be proactive. If you miss a blood test, reschedule it right away
- Be aware of possible signs and symptoms (described on the following pages) of the most common side effects and call your doctor or nurse right away if you experience them
- Take action to reduce your risk of infection and other serious side effects that can occur while your blood counts are still low
- Educate yourself about side effects of treatment with REVLIMID

- Be sure your doctor or nurse knows about all the other medicine(s) you are taking – It is very important for your doctor or nurse to know about all prescription medicines, over-the-counter and herbal medicines, vitamins, and dietary supplements

Side effects can occur while you are taking REVLIMID. These side effects may be serious:

- Dose interruption: A period of time when you are not taking REVLIMID
- Dose reduction: A lowering of your dose of REVLIMID

Complete blood counts (CBCs): Laboratory tests that count the total number of cells in a blood sample

A full Glossary may be found on page 29.
It is important for your doctor or nurse to monitor your blood counts while you are taking REVLIMID.

Fever occurred in more than 20% of patients with del 5q MDS taking REVLIMID. Please call your doctor or nurse if your temperature is 100.5°F or higher.

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 60% 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 in the arteries, veins, and lungs happen more often in people who take REVLIMID.

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,
- have high blood pressure,
- you smoke,
- you have been told you have high level of fat in your blood (hyperlipidemia),
- and 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, during treatment with REVLIMID, if you get any of these signs or symptoms:

- Blood clot in lung, arm or leg: shortness of breath, chest pain, or arm or leg swelling.
- Heart attack: chest pain that may spread to arms, neck, jaw, back or stomach area, feeling sweated, shortness of breath, feeling sick or vomiting.
- Stroke: sudden numbness or weakness, especially on one side of the body, severe headache or confusion, or problems with vision, speech or balance.

It is important for your doctor or nurse to monitor your blood counts while you are taking REVLIMID.

To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, in pocket and Important Safety Information on pages 2-5.
REVLIMID® (lenalidomide) is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require 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 under 18 years of age.

What are other possible side effects of REVLIMID® (lenalidomide)?

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).**

  People with MM who receive REVLIMID and melphalan and a blood stem cell transplant have a higher risk of developing new cancers, including certain blood cancers (acute myelogenous leukemia or AML and myelodysplastic syndrome or MDS) 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: 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, bleeding or bruising more easily than normal and feeling very tired. Your healthcare provider will do blood tests to check your liver function during treatment with REVLIMID.

- **Serious skin reactions.**

  Serious allergic reactions and serious 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 serious allergic reaction or serious skin reaction: swelling of your face, eyes, lips, tongue, throat; trouble swallowing or breathing, skin rash, hives or peeling of your skin and blisters.

- **Allergic reactions.**

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

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.

Worsening of your tumor (tumor flare reaction)

Tell your healthcare provider if you get any of these symptoms while taking REVLIMID: tender swollen lymph nodes, low-grade fever, pain or rash.

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.

Rash and itching

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

**If you get a rash while taking REVLIMID, do not treat it yourself. Show the rash to your doctor or nurse.**
REVLIMID® (lenalidomide) is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require blood transfusions.

REVLIMID should not be used to treat people who have chronic lymphocytic leukemia (CLL). It is not known if REVLIMID is safe and effective in children under 18 years of age.

Gastrointestinal (GAS•troh•in•TES•tih•nul): Refers to the stomach and intestines. A full Glossary may be found on page 29.

What are other possible side effects of REVLIMID® (lenalidomide)? (continued)

Gastrointestinal disorders
Patients with del 5q MDS taking REVLIMID have reported diarrhea (49%), constipation (24%), nausea (24%), vomiting (10%), dry mouth (7%), or upper abdominal pain (8%).

Diarrhea
Nearly half of the patients (49%) reported diarrhea. Some patients taking REVLIMID had watery stools that lasted more than a few days. Ask your doctor if a diet of bananas, rice, applesauce, and toast may help mild diarrhea. 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%) and 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%), arthralgia (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.

Fever and cough
Some patients taking Revlimid developed a fever (21%). Additionally, during treatment some patients reported having a cough (20%). Tell your doctor if you develop either of these.

Tell your doctor or nurse right away if you have any side effects while taking REVLIMID.

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

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, in pocket and Important Safety Information on pages 2-5.
REVLMID® (lenalidomide) is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require blood transfusions.

REVLMID 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 REVLMID is safe and effective in children under 18 years of age.

REVLMID® (rev-li-mid)
(lenalidomide) Capsules

Read the Medication Guide that comes with REVLMID 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 REVLMID?

- Before you begin taking REVLMID, you must read and agree to all of the instructions in the REVLMID REMS® program (formerly known as the RevAssist® program).
- REVLMID 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 REVLMID.

REVLMID is similar to the medicine thalidomide (THALOMID®). We know thalidomide can cause severe life-threatening birth defects. REVLMID has not been tested in pregnant females. REVLMID has harmed unborn animals in animal testing.

Females must not get pregnant:
- for at least 4 weeks before starting REVLMID
- while taking REVLMID
- during any breaks (interruptions) in your treatment with REVLMID
- for at least 4 weeks after stopping REVLMID

If you become pregnant while taking REVLMID, 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

REVLMID can pass into human semen:
- 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 REVLMID, during any breaks (interruptions) in your treatment with REVLMID, and for 4 weeks after stopping REVLMID.
- 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 REVLMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLMID. If a female becomes pregnant with your sperm, the baby may be exposed to REVLMID 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 blood counts should be checked often during the first several months of treatment, and then at least monthly thereafter. 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
- if you smoke
- if you have been told that 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.

Call your healthcare provider or get medical help right away, during treatment with Revlimid, 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.

REVLIMID® (lenalidomide) is used to treat patients who have low- or intermediate-1–risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require 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 under 18 years of age.

What is REVLIMID?

REVLIMID is a prescription medicine used to treat people:
- with multiple myeloma (MM) in combination 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.

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

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, in pocket and Important Safety Information on pages 2-5.
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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 open, break or chew 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.

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

Revlid® (lenalidomide) is used to treat patients who have low- or intermediate-1-risk myelodysplastic syndromes (MDS) where part of chromosome 5 is missing (del 5q). These patients have low red blood cell counts (anemia) that require blood transfusions.

Revlid® 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 Revlid® is safe and effective in children under 18 years of age.

What are the possible side effects of Revlid®?
Revlid® may cause serious side effects, including:

- "What is the most important information I should know about Revlid®?"
- Increased risk of death in people who have chronic lymphocytic leukemia (CLL). People with CLL who take Revlid® have an increased risk of death compared to people who take the medicine chlorambucil. Revlid® 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 Revlid® if you have CLL unless you are participating in a controlled clinical trial.
- Risk of new cancers (malignancies). People with multiple myeloma who receive Revlid® and melphalan and a blood stem cell transplant have a higher risk of developing new cancers, including certain blood cancers (acute myelogenous leukemia or AML and myelodysplastic syndrome or MDS) and a type of lymphoma called Hodgkin lymphoma. Talk with your healthcare provider about your risk of developing new cancers if you take Revlid®. Your healthcare provider will check you for new cancers during your treatment with Revlid®.
- 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 Revlid®.
- Serious skin reactions. Serious allergic reactions and serious skin reactions can happen with Revlid® and may cause death. Call your healthcare provider right away if you develop any of these signs or symptoms of serious allergic reaction or serious skin reaction: swelling of your face, eyes, lips, tongue, throat, trouble swallowing or breathing, skin rash, hives or peeling of your skin and blisters.
- 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 Revlid®: tender swollen lymph nodes, low-grade fever, pain, or rash.

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

Common side effects of Revlid® include:
- diarrhea
- constipation
- itching
- rash
- tiredness
- swelling of the limbs and skin
- nausea
- fever
- cough

These are not all the possible side effects of Revlid®. 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 Revlid®?
- Store Revlid® at room temperature between 68°F to 77°F (20°C to 25°C).
- Return any unused Revlid® to Celgene or your healthcare provider.

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

General information about Revlid®
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take Revlid® for conditions for which it was not prescribed. Do not give Revlid® 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 Revlid® that is written for health professionals.

What are the ingredients in Revlid®?
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

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Glossary

**Anemia** (a•NEE•mee•a): A condition in which the number of RBCs is below normal

**Bone marrow** (bone MY•AR•oh): The soft, sponge-like tissue in the center of bones that makes RBCs, WBCs, and platelets

**Chromosome** (KRO•h•muh•some): A structure that contains your genetic information, or DNA

**Complete blood counts (CBCs)**: Laboratory tests that count the total number of cells in a blood sample

**Cytopenia** (SY•toh•PEE•nee•uh): Reduction in the number of blood cells

**Deletion 5q** (del 5q): An abnormality where part of chromosome 5 is missing

**Dose interruption**: A period of time when you are not taking REVLIMID

**Dose reduction**: A lowering of your dose of REVLIMID

**Gastrointestinal (GAS•troh•in•TES•tih•nul)**: Refers to the stomach and intestines

**Medication Guide**: Patient information approved by the US Food and Drug Administration (FDA)

**Myelodysplastic syndromes (MDS)** (MY•eh•loh•dis•PLAS•tik SIN•dromz): Derived from myelo, which means marrow, and dysplasia, which means abnormal growth. A group of diseases in which the bone marrow does not make enough healthy blood cells

**Neutropenia** (noo•troh•PEE•nee•uh): A condition in which the number of neutrophils (the most numerous type of WBC, which helps fight infection) is below normal in the blood

**Platelets** (PLATE•lets): Blood cells that are essential for blood clotting

**Red blood cells (RBCs)**: The cells that carry oxygen to the body’s tissues

**Stem cell**: Produced in the bone marrow and matures into a healthy cell, such as an RBC, WBC, or platelet

**Thrombocytopenia** (THROM•bok•tob•PEE•nee•uh): A condition in which the number of platelets, or thrombocytes, is below normal, resulting in the tendency to bruise and bleed more easily

**Transfusions** (trans•FYOO•zhunz): Add parts of blood or whole blood into the bloodstream

**White blood cells (WBCs)**: The cells that help the body fight infection

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Getting Started With REVIMID

Deletion 5q myelodysplastic syndromes

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

For additional information about REVIMID® (lenalidomide) and REVIMID REMS®, please call the Celgene Customer Care Center at 1-888-423-5436 or visit www.REVLIMID.com.

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