



Treating multiple myeloma with REVLIMID

REVLIMID is a prescription medicine used to treat adults 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).

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.

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

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

Please see accompanying full Prescribing Information, including Boxed WARNINGS and Medication Guide, for REVLIMID, and Important Safety Information on pages 2-10.

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 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 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.

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.

Important Safety Information (continued)

- 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 a female becomes pregnant with your sperm, you should call your HCP 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); and
- 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 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

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 Medication Guide for a complete list of ingredients in REVLIMID.

Important Safety Information (continued)

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 the 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.
 - 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.

Important Safety Information (continued)

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), myelodysplastic syndromes (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 and severe allergic reactions** can happen with REVLIMID and may cause death.

Call your healthcare provider right away if you develop any of the following signs or symptoms during treatment with REVLIMID:

- a red, itchy, skin rash
- severe itching
- peeling of your skin or blisters
- fever

Get emergency medical help right away if you develop any of the following signs or symptoms during treatment with REVLIMID:

- swelling of your lips, mouth, tongue, or throat
- trouble breathing or swallowing
- raised red areas on your skin (hives)
- a very fast heartbeat
- You feel dizzy or faint
- **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.

Important Safety Information (continued)

- **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 or weakness
- fever
- itching
- swelling of your arms, hands, legs, feet, and skin
- sleep problems (insomnia)
- headache
- muscle cramps or spasms
- shortness of breath
- cough, sore throat, and other symptoms of a cold
- upper respiratory tract infection or bronchitis
- inflammation of the stomach and intestine (“stomach flu”)
- nose bleed
- shaking or trembling (tremor)
- joint aches
- pain in your back or stomach area (abdomen)

These are not all of 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 accompanying full Prescribing Information, including Boxed WARNINGS and Medication Guide, for REVLIMID.

Welcome

You're taking an important step in treating your multiple myeloma with REVLIMID. While your healthcare team is your best source of information, this guide provides answers to common questions you may have.

Table of contents

- Learn about multiple myeloma 15
- Learn more about REVLIMID 21
- Clinical studies of REVLIMID 24
- REVLIMID REMS® Program 31
- REVLIMID dosing 35
- Learn about side effects of REVLIMID 43
- Celgene Patient Support® 57
- Glossary 63

Learn about multiple myeloma

The more you know about multiple myeloma, the more involved you can be when making decisions about your care with your healthcare team.

Understanding multiple myeloma

Multiple myeloma is a serious disease. This kit was designed to help you face it head on. As you learn about the illness and become more aware of what happens in your body, you may feel better prepared.

Empower yourself

Ask questions and stay involved in your treatment.

What is multiple myeloma?

Multiple myeloma (MM) is a chronic cancer of **plasma cells** that live in your **bone marrow**. Healthy plasma cells are a critical part of the immune system and play an important role in fighting infection. In MM, cancerous plasma cells build up and cause damage, including:



Bone damage can cause bone pain and weak or broken bones



Low red blood cell counts (anemia) can cause weakness, shortness of breath, and dizziness



Excess calcium in the blood, a frequent result of myeloma cell activity, can put extra strain on the kidneys



Kidney problems can cause weakness and leg swelling



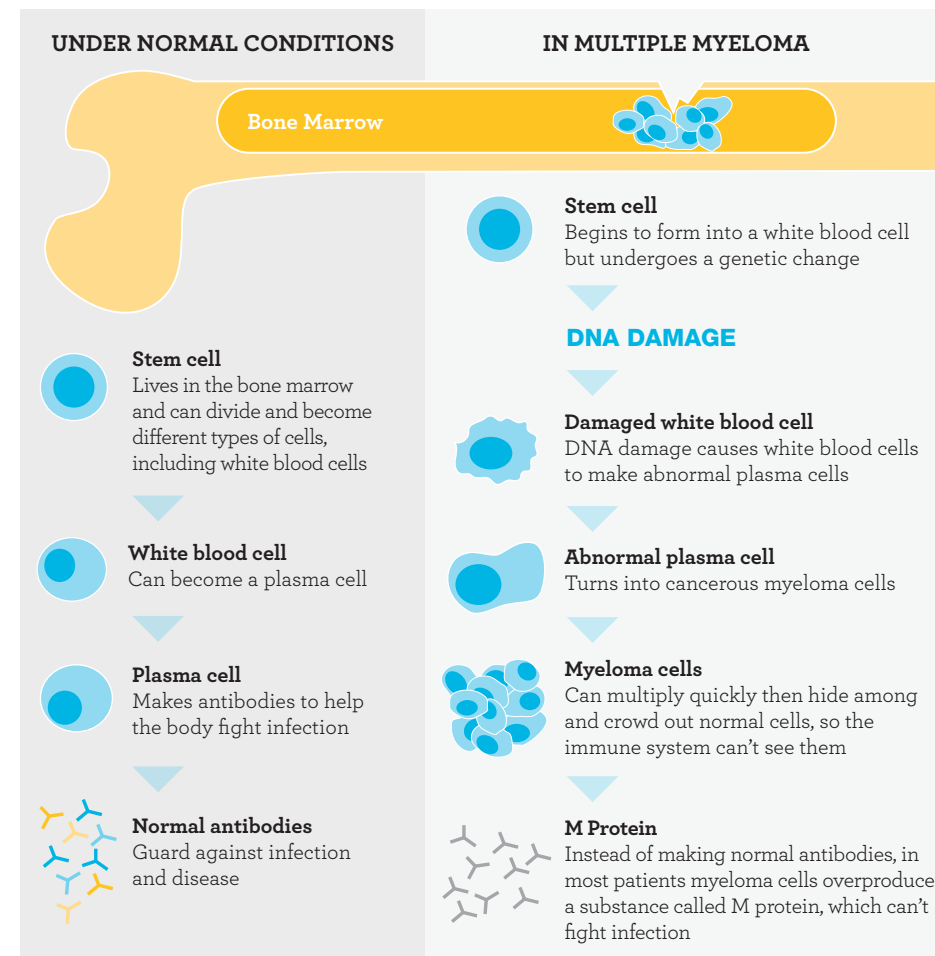
Low white blood cell count (leukopenia) can make it harder to fight infections

Treatment is important

There is no cure for MM, but a long-term treatment strategy can help you manage it.

How multiple myeloma develops

The bone marrow makes different types of immune cells, including plasma cells. In multiple myeloma, plasma cells become cancerous—or myeloma—cells. These cells can disguise themselves to look harmless so they go undetected and multiply, crowding out healthy cells in the marrow. Myeloma cells also release chemical messengers that can stop healthy immune cells from working.



Learn more about REVLIMID

The #1 most prescribed* treatment for multiple myeloma, REVLIMID is an immune-modulating treatment, known as an IMiD[®] agent, with proven anti-myeloma effects.

*Claims data 02/2016-05/2019. Source: IntrinsiQ Data © 2019. IntrinsiQ Specialty Solutions, Inc.

Learn more about REVLIMID

RevlimidREMS[®]

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

Please see accompanying full Prescribing Information, including Boxed WARNINGS and Medication Guide, for REVLIMID, and Important Safety Information on pages 2-10.


Revlimid[®]
(lenalidomide)_{capsules} 21

REVLIMID gives you multiple ways to fight multiple myeloma

REVLIMID is an immune-modulating therapy, known as an IMiD[®] agent, with proven anti-myeloma effects. REVLIMID is an oral therapy that was shown to work in 3 ways in animal models and **in vitro***:

***In vitro**: In a test tube or glass; outside of a living organism.



STRIKE

Targets and kills myeloma cells



STIMULATE

Helps your immune system recognize and destroy myeloma cells



STARVE

Prevents new myeloma cell growth by starving them of blood



REVLIMID is a once-daily capsule taken at home or wherever is convenient for you



REVLIMID is not a traditional chemotherapy, injection or infusion



REVLIMID is the #1 most prescribed* treatment for multiple myeloma

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

*Claims data 02/2016-05/2019. Source: IntrinsiQ Data © 2019. IntrinsiQ Specialty Solutions, Inc.

About the study

A study of 1623 patients looked at the efficacy and safety of REVLIMID with dexamethasone as a treatment for newly diagnosed multiple myeloma patients who had not received a stem cell transplant.

The study evaluated:

- Progression-Free Survival (PFS)—how long a patient lives without the disease getting worse
- Overall Survival (OS)—the length of time patients lived since the start of treatment
- Overall Response Rate (ORR)—how patients responded to treatment overall

Patients were divided into 3 groups:

- The first group took REVLIMID with dexamethasone continuously*
- The second group took REVLIMID with dexamethasone for 18 months
- The third group took a combination of the drugs melphalan, prednisone, and thalidomide for 18 months

*Until the multiple myeloma got worse or they experienced intolerable side effects.

Patients who took REVLIMID with dexamethasone continuously experienced:



Longer Progression-Free Survival (PFS)

Compared to patients who took REVLIMID with dexamethasone for only 18 months, or a combination of melphalan, prednisone, and thalidomide



Longer Overall Survival (OS)

Compared to patients who took a combination of melphalan, prednisone, and thalidomide



Higher Overall Response Rate (ORR)

Compared to 73% of patients who took REVLIMID and dexamethasone for only 18 months and 62% of patients who took the combination of melphalan, prednisone, and thalidomide

Important Safety Information (continued)

What is the most important information I should know about 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

About the studies

Two studies (Study 1: 460 patients, Study 2: 614 patients), looked at the efficacy and safety of REVLIMID as a maintenance therapy after an autologous hematopoietic stem cell transplant (auto-HSCT). Half of the patients were treated with REVLIMID every day until the disease progressed, side effects became intolerable or patient withdrawal for another reason, while the other half received no maintenance treatment.

Patients who took REVLIMID maintenance therapy experienced:

Longer Progression-Free Survival (PFS)

Studies 1 and 2 evaluated PFS—how long a patient lives without their disease getting worse.

Initial analyses were conducted in 2009 and 2010 for Study 1 and Study 2, respectively.

- Patients who took REVLIMID maintenance therapy experienced a median* PFS of 2.8 years in Study 1, and 3.4 years in Study 2
- Patients who took no maintenance therapy experienced a median* PFS of 1.6 years (Study 1) and 1.9 years (Study 2)

These studies were updated again for PFS in March 2015 as shown on the next page.

Important Safety Information (continued)

What are the possible side effects of REVLIMID?

The most common side effects of REVLIMID include: diarrhea, rash, nausea, constipation, tiredness or weakness, fever, itching, swelling of your arms, hands, legs, feet, and skin, sleep problems (insomnia), headache, muscle cramps or spasms, shortness of breath, cough, sore throat, and other symptoms of a cold, upper respiratory tract infection or bronchitis, inflammation of the stomach and intestine (“stomach flu”), nose bleed, shaking or trembling (tremor), joint aches, and pain in your back or stomach area (abdomen).

Updated Analyses

In Study 1, patients who took REVLIMID maintenance therapy delayed disease progression a median* of 3.8 years longer than patients who took no maintenance therapy



In Study 2, patients who took REVLIMID maintenance therapy delayed disease progression a median* of 1.9 years longer than patients who took no maintenance therapy

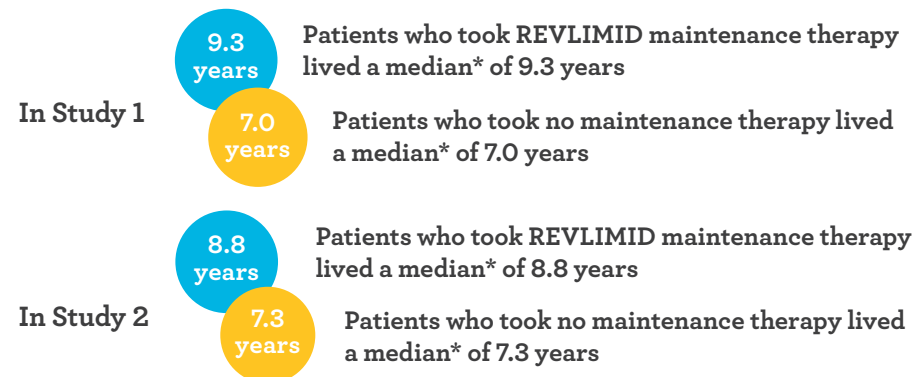


*“Median” means half of the patients had a larger result while half of the patients had a smaller result.

Additional REVLIMID maintenance therapy clinical data

These studies were not designed to evaluate Overall Survival (OS)—the length of time patients were alive following the start of treatment. Therefore, it cannot be concluded that REVLIMID caused the differences observed between the 2 groups. Below is the Overall Survival data from the studies:

Overall Survival (OS)



About the studies

Two studies (Study 1: 351 patients, Study 2: 353 patients), looked at the efficacy and safety of REVLIMID with dexamethasone as a treatment for multiple myeloma patients who received at least one prior therapy. The studies evaluated Time to Progression (TTP)—the length of time on treatment before MM worsened, and Overall Response Rate (ORR)—how many patients responded to treatment.

Patients were divided into 2 groups:

- The first group took REVLIMID with dexamethasone
- The second group took placebo with dexamethasone

Patients who took REVLIMID with dexamethasone experienced:

Longer TTP

In Study 1, the TTP was a median* 9.2 months longer than in patients who took placebo with dexamethasone

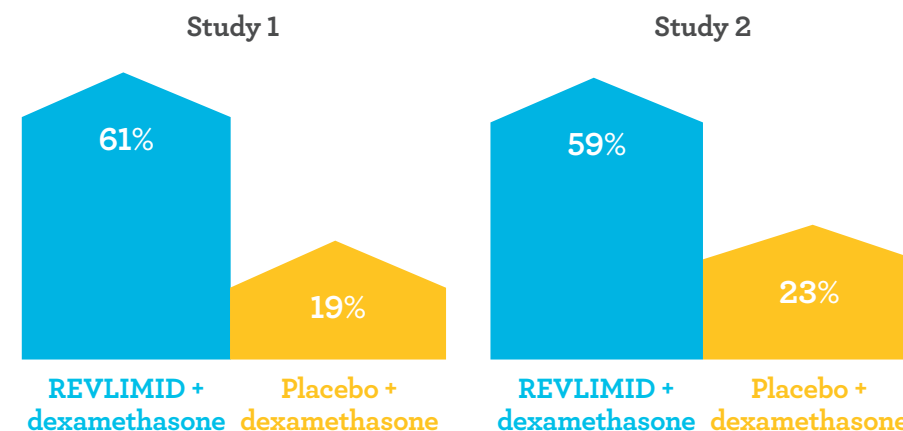


In Study 2, the TTP was a median* 7.4 months longer than in patients who took placebo with dexamethasone



*“Median” means half of the patients had a larger result while half of the patients had a smaller result.

Higher Overall Response Rate (ORR)



Important Safety Information (continued)

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?”
- Do not take REVLIMID if you are allergic to lenalidomide or any of the ingredients in REVLIMID. See the Medication Guide for a complete list of ingredients in REVLIMID

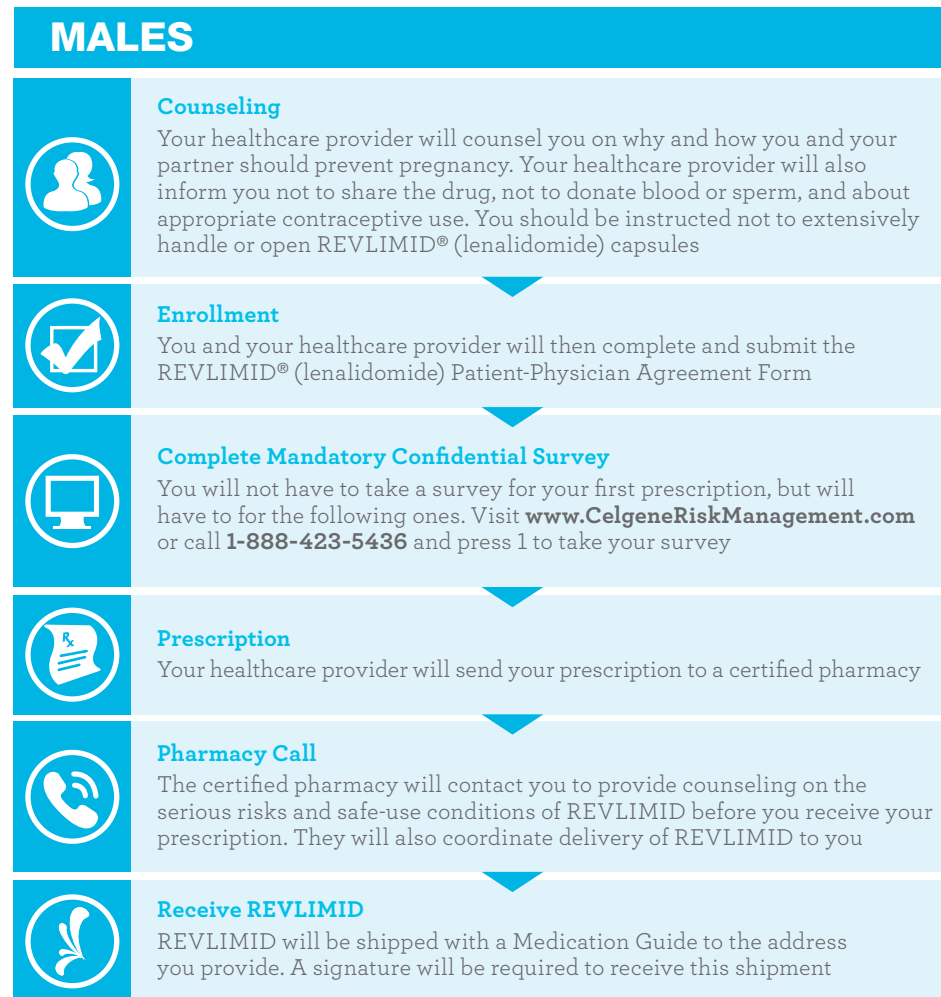
REVLIMID REMS^{®*} Program

*Risk Evaluation and Mitigation Strategy

Every patient who takes REVLIMID must enroll in the REVLIMID REMS[®] program.

REVLIMID REMS® Program

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



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.



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 dosing




REVLIMID is prescribed differently, depending on where you are in your multiple myeloma treatment. Your doctor or healthcare provider will prescribe you a specific dose suited to your needs.

REVLIMID with dexamethasone

For newly diagnosed multiple myeloma patients not receiving a stem cell transplant, REVLIMID is taken in combination with dexamethasone. Your healthcare team will prescribe you a specific dose and dosing schedule for each medicine based on your individual needs. It's important that you continue this dosing for as long as you are prescribed REVLIMID.

Sample 28-day dosing cycle

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

-  Take REVLIMID 25 mg every day for 21 days, as shown
-  Take dexamethasone 40 mg on days 1, 8, 15, and 22, as shown*
-  **Do not** take REVLIMID or dexamethasone on days 23-28


*Patients older than age 75 years should use 20 mg of dexamethasone on days 1, 8, 15, and 22 of the treatment cycle.

REVLIMID maintenance therapy

REVLIMID is taken by itself (without dexamethasone) as maintenance therapy in patients who have had an autologous hematopoietic stem cell transplant. Your healthcare team will prescribe you an exact dose and dosing schedule for REVLIMID maintenance therapy. This maintenance dosing should continue unless your myeloma gets worse, or if you have side effects that you are unable to tolerate.

Sample 28-day dosing cycle

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

-  Take REVLIMID 10 mg every day for 28 days, as shown
- The standard starting dose for most patients is:
- One 10-mg pill, once every day
 - After three 28-day cycles of maintenance treatment, the dose of REVLIMID can be increased by your doctor to 15 mg once daily, if tolerated




Please see accompanying full Prescribing Information, including Boxed WARNINGS and Medication Guide, for REVLIMID, and Important Safety Information on pages 2-10.

REVLIMID with dexamethasone

For patients who received at least one prior therapy, REVLIMID is taken in combination with dexamethasone. Your healthcare team will tell you which dose of each medicine is right for you. It's important that you continue with this dosing for as long as you are prescribed REVLIMID.

Sample 28-day dosing cycle

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

-  Take REVLIMID 25 mg every day for 21 days, as shown
-  Take dexamethasone 40 mg on days 1-4, 9-12, and 17-20, as shown*
-  **Do not** take REVLIMID or dexamethasone on days 22-28

* This was the dosing schedule in the clinical trials. Your healthcare team may adjust your dose

*In the clinical trials the dose of dexamethasone was 40mg once daily on days 1-4, 9-12, and 17-20 of each 28-day cycle for the first 4 cycles of therapy, and then reduced to 40mg once daily on days 1-4 every 28 days.

To download a customizable dosing calendar, visit REVLIMID.com/calendar

Important things to remember when taking 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, 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



REVLIMID comes in 6 capsule strengths: 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg. Your doctor will tell you the dose that is right for you

Important things to remember when taking REVLIMID (continued)

Your doctor may change your dose

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

How to store REVLIMID

It is important to store REVLIMID in a safe place away from children. Do not share your REVLIMID prescription with anyone. It may cause birth defects and other serious side effects.

Keep REVLIMID in a cool, dry place. REVLIMID should be stored at room temperature, within a range of 68°F to 77°F (20°C to 25°C) with excursions permitted to 59°F to 86°F (15°C to 30°C).

What should I avoid while taking REVLIMID?

- **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.** See the Medication Guide, included in this kit, and refer to the following sections: “What is the most important information I should know about REVLIMID?,” “Who should not take REVLIMID?,” and “What should I avoid while taking REVLIMID?”
- **Do not share REVLIMID with other people.** It may cause birth defects and other serious problems
- **Do not donate blood** while you take REVLIMID, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID. If someone who is pregnant gets your donated blood, her baby may be exposed to REVLIMID and may be born with birth defects

Learn about the possible side effects of REVLIMID

Side effects

You may experience side effects while taking REVLIMID. Your doctor can adjust your dosage of REVLIMID to help reduce them so you can stay on treatment and receive its benefits longer.

Serious side effects of REVLIMID:	Common side effects of REVLIMID in MM include:
Birth defects	Diarrhea
Increased risk of death in people who have chronic lymphocytic leukemia (CLL)	Rash
Risk of new cancers (malignancies)	Nausea
Severe liver problems, including liver failure and death	Constipation
Severe allergic reactions and severe skin reactions	Tiredness or weakness
Tumor lysis syndrome (TLS)	Fever
Worsening of your tumor (tumor flare reaction)	Itching
Thyroid problems	Swelling of the limbs and skin
Risk of early death in MCL	Cough and other cold-like symptoms

These are not all of the possible side effects of REVLIMID. See “What are the possible side effects of REVLIMID?” on pages 8-10 for a comprehensive list and additional information. Tell your healthcare team 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 heartbeats). 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 multiple myeloma who are taking REVLIMID with dexamethasone

What to do if you experience some common side effects

It's good to be prepared in the event you experience some side effects with REVLIMID. Here is more information about specific side effects, and steps you can take to manage them. Remember to always discuss side effects with your healthcare team.

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

Diarrhea

Treatment with REVLIMID can cause diarrhea. Diarrhea happens when your stools become watery and you go to the bathroom much more often than usual. Your doctor needs to know if you have diarrhea. Diarrhea can cause weight loss, fluid loss (dehydration), poor appetite, and weakness.

Diarrhea may cause complications, such as:

- Dizziness
- Fever
- Sore or bleeding rectal area

If you have any of these complications or if you have diarrhea and cramps for more than a day, call your doctor or nurse right away. If you have diarrhea, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Are there foods I should eat when I have diarrhea?
- Are there foods I should not eat when I have diarrhea?
- How much liquid should I drink each day?
- Is there medicine I can take to help with the diarrhea?

Itching and rash

Treatment with REVLIMID can cause pruritus, also known as itchiness. Itching can be uncomfortable. If you scratch a lot, it can lead to breaks in the skin and infection. Rash is another common side effect of REVLIMID. Rash may range in severity from mild irritation to obvious changes in skin color. **Some patients have had severe skin reactions that required immediate medical attention or were fatal. If you get any kind of rash, tell your healthcare provider immediately.**

If you feel itchy or you notice a rash on your body, tell your doctor or nurse. He or she will want to know about any skin changes you have.



You may want to ask your healthcare team:

- Should I take hot or cold baths?
- Is there anything I can put on my skin that may help the itching?
- Should I avoid washing my clothes in harsh detergents?
- Should I avoid the sun?
- Are there any medicines that I can take that may help relieve the itching?

Nausea

Treatment with REVLIMID can cause nausea. Nausea is an uneasy or unsettled feeling in the stomach. It's often accompanied by the urge to vomit, but doesn't always lead to vomiting. Some other ways people describe nausea are "feeling sick to my stomach," "queasy," or "upset stomach."

If you have nausea, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Are there foods I should eat when I have nausea?
- Are there foods I should avoid when I have nausea?
- Should I drink more or less water or liquids?
- Would exercise help?
- Are there medicines that may help?

Constipation

Treatment with REVLIMID can cause constipation. When you have constipation, you do not have as many bowel movements as you normally do. You may also feel bloated and uncomfortable and have hard, painful bowel movements.

If you have constipation, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Are there foods I should eat when I have constipation?
- Should I drink more water or liquids?
- Would exercise help?
- Should I keep track of my bowel movements?
- Are there medicines that may help?

Fatigue

Fatigue is a common side effect of treatment with REVLIMID. Sometimes people describe fatigue as feeling tired, weak, exhausted, heavy, or slow. Fatigue can affect people physically, mentally, and emotionally.

If you feel tired, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Should I change my activity level?
- Would exercise help me feel less tired?
- Will sleeping more help my fatigue?
- Should I eat certain foods or drink certain liquids when I am feeling tired?
- Is there medicine that I can take to help alleviate the fatigue?
- If I am already taking a medicine that makes me feel tired, will REVLIMID make me more tired?

Fever

Treatment with REVLIMID can cause a fever. A fever is a body temperature that is higher than normal, which is 98.6°F for an adult. Having a fever may be uncomfortable, but usually isn't a cause for concern unless it reaches 103°F or higher.

If you have a fever, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Are there any dietary restrictions I should follow?
- Should I drink more or less water or liquids?
- Are there medicines that may help?

Swelling of the limbs and skin

Treatment with REVLIMID can cause swelling of the limbs (your arms, hands, legs, and feet) and skin, called edema. This swelling or puffiness of the tissue directly under your skin is caused by excess fluid trapped in your body's tissues. Edema is most commonly noticed in the hands, arms, feet, ankles, and legs. Your skin may appear stretched or shiny. With edema, you may experience swelling after sitting or standing for a long period of time.

If you have swelling of the limbs and skin, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Are there any foods I should avoid?
- Should I drink more or less water or liquids?
- Would exercise help?
- Are there medicines that may help?

Cough

Treatment with REVLIMID can cause you to cough, have a sore throat, and other cold-like symptoms. Coughing is your body's way of keeping your throat and airways clear. Irritants in your throat and airways stimulate your nerves to send a cough impulse to your brain. The brain signals the muscles of your abdomen and chest wall to give a strong push of air to your lungs to try to get rid of the irritant.

If you have a cough, tell your doctor or nurse. He or she will want to know about any side effects you have.



You may want to ask your healthcare team:

- Should I drink more water or liquids?
- Should I take cough drops?
- Would a vaporizer help?
- Are there medicines that may help?

Remember to keep an open line of communication with your healthcare team. They can help answer questions you may have about side effects or your treatment with REVLIMID.

Celgene Patient Support®

Celgene Patient Support® wants to make sure you get the help you need to start your treatment with REVLIMID.

No matter what type of insurance you have, or if you don't have insurance or enough coverage, Celgene Patient Support® is available to help answer your questions.



Celgene Patient Support® A single source for access support

At Celgene Patient Support®, we care about making sure you get the answers you need. That's why our Specialists are ready to help answer questions about the insurance approval process. And you may need help paying for REVLIMID. Celgene Patient Support® can help you and your loved ones understand the programs and services available to you.

Depending on your situation, there are programs and organizations that may help you pay for REVLIMID.



Celgene Commercial Co-pay Program
for eligible patients with commercial or private insurance (including healthcare exchanges)*



Independent third-party organizations
for patients who are unable to afford their medication (including patients with Medicare, Medicaid, or other government-sponsored insurance)†



Celgene Patient Assistance Program (PAP)
for qualified patients who are uninsured or underinsured‡

* Other eligibility requirements and restrictions apply. Please see full Terms and Conditions on the Celgene Patient Support® website.

† Financial and medical eligibility requirements vary by organization.

‡ Patients must meet specified financial and eligibility requirements to qualify for assistance.

Enrollment in Celgene Patient Support® is simple—choose the option that is best for you.



Enroll online at
www.celgenepatientsupport.com



Call us at **1-800-931-8691**,
Monday–Friday 8 AM–8 PM ET
(translation services available)



Email us at patientsupport@celgene.com



Fax a completed application to
1-800-822-2496

Additional helpful resources

Multiple Myeloma Research Foundation (MMRF)

www.themmr.org
203-229-0464

Cancer Hope Network

www.cancerhopenetwork.org
877-HOPENET

Caring Bridge

www.caringbridge.org
651-452-7940

National Comprehensive Cancer Network

www.nccn.org
215-690-0300

Cancer Support Community

www.cancersupportcommunity.org
888-793-9355

The Myeloma Beacon

www.myelomabeacon.com

Myeloma Crowd

www.myelomacrowd.org

International Myeloma Foundation

www.myeloma.org
800-452-CURE

Lotsa Helping Hands

www.lotsahelpinghands.com

Support and guidance for caregivers:

Family Caregiver Alliance

www.caregiver.org
800-445-8106

Well Spouse Association

www.wellspouse.org
800-838-0879

These sites are not owned or managed by Celgene Corporation and Celgene does not take responsibility for their content.

Glossary

Glossary

Anemia

a shortage of red blood cells, which can cause patients to be pale, weak, and tired.

Antibody

specialized cells of the immune system, which can recognize harmful organisms that invade the body and help fight infection.

Autologous hematopoietic stem cell transplant

the infusion of healthy cells designed to establish marrow and immune function in patients whose bone marrow or immune system is damaged or defective.

Bone marrow

a soft spongy tissue in which blood cells are produced that occupies the cavities of bones.

Constipation

a condition defined by difficulty in the passage of hardened feces.

Deep vein thrombosis

a condition marked by the formation of a blood clot in a deep vein that can cause leg pain or swelling.

Dexamethasone

a synthetic steroid medication used in the treatment of many conditions.

Fatigue

weariness or exhaustion.

Immune system

the bodily system that protects the body from foreign substances, cells, and tissues.

Leukopenia

a condition characterized by a shortage of white blood cells, which can make it very hard for the body to fight infections.

Melphalan

an oral drug that helps inhibit or prevent the growth and spread of tumors or malignant cells.

M Protein

a type of antibody that does not fight infection and is produced in excess by multiple myeloma patients.

Myeloma cell

a malignant plasma cell in the bone marrow.

Nausea

a feeling of stomach distress with distaste for food and an urge to vomit.

Glossary

Neutropenia

a condition characterized by abnormally few white blood cells, that causes an increased susceptibility to infection.

Overall Response Rate (ORR)

the percentage of patients whose cancer shrinks or disappears after treatment.

Overall Survival (OS)

the length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive. In a clinical trial, measuring the overall survival is one way to see how well a new treatment works.

Plasma cells

a type of white blood cell that makes large amounts of a specific antibody.

Prednisone

a steroid used to relieve rheumatic and allergic conditions and to treat many conditions including multiple myeloma.

Progression-Free Survival (PFS)

the length of time during and after the treatment of a disease that a patient lives with the disease, but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works.

Stem cells

a cell that is capable of becoming many other types of cells.

Thalidomide

an immunomodulatory agent used in the treatment of multiple myeloma.

Time to Progression (TTP)

the length of time from the date of diagnosis or the start of treatment for a disease until the disease starts to get worse or spread to other parts of the body. In a clinical trial, measuring the time to progression is one way to see how well a new treatment works.

Tumor flare reaction

worsening of a tumor that is often caused by cancer treatment.

Tumor Lysis Syndrome (TLS)

a group of metabolic disturbances that may occur after the initiation of cancer treatment.

Call your healthcare professional for medical advice about side effects. To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed WARNINGS and Medication Guide, for REVLIMID, and Important Safety Information on pages 2-10.

RevlimidREMS[®]


Revlimid[®]
(lenalidomide) capsules
2.5 · 5 · 10 · 15 · 20 · 25 mg

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



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

© 2020 Celgene Corporation 01/20 US-REV-19-0673