



Maintenance Therapy for Multiple Myeloma

A next step after your autologous hematopoietic stem cell transplant (auto-HSCT)

What is REVLIMID® (lenalidomide)?

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, Lenalidomide REMS.

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

Boxed WARNINGS

Selected Important Safety Information

Some of the serious side effects of REVLIMID include:

- Possible birth defects (deformed babies) or death of an unborn baby.
- Can cause harm to an unborn baby, blood clots, and low blood cell counts.

Please see additional Important Safety Information throughout this document.

Please see detailed REVLIMID Important Safety Information on pages 2-24, as well as full [Prescribing Information](#), including [Boxed WARNINGS](#) and [Medication Guide](#).

What's Inside

Your autologous hematopoietic stem cell transplant (auto-HSCT) is an important step against multiple myeloma. An auto-HSCT can be very effective, and there's a way you may extend your response: post-transplant maintenance therapy. REVLIMID® (lenalidomide) is the only myeloma treatment that is FDA-approved for maintenance therapy after an auto-HSCT.

Important Safety Information

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

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 Lenalidomide REMS program. Before prescribing REVLIMID, your healthcare provider will explain the Lenalidomide REMS program to you and have you sign the Patient-Physician Agreement Form.

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Benefits of maintenance therapy

Maintenance therapy is a proven strategy to extend the response from a stem cell transplant (SCT). Maintenance therapy may control the growth of residual myeloma cells.

An SCT is effective in helping multiple myeloma (MM) patients significantly reduce myeloma cells and restore the bone marrow's ability to produce healthy blood cells. Many doctors recommend maintenance therapy following an SCT because it plays an important part in extending the response from a transplant as long as possible.

Why maintenance therapy helps:

- 100 million MM cells could remain in your body, even after a complete response to an SCT
- Without maintenance treatment, your immune system can weaken sooner and MM may return earlier

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

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.

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REVLIMID® (lenalidomide) maintenance therapy

REVLIMID is approved to be taken without any other medications for maintenance treatment after an autologous SCT.



REVLIMID is not a traditional chemotherapy, injection, or infusion.



REVLIMID is a once-daily capsule, taken at home or wherever is convenient for you. Dosing for REVLIMID maintenance therapy can be adjusted to help reduce side effects, and help people stay on—and receive the benefits of—maintenance therapy longer.

REVLIMID is the only FDA-approved multiple myeloma maintenance treatment after an auto-HSCT.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

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.

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REVLIMID® (lenalidomide) maintenance therapy delayed disease progression

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

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 (Study 1) and 3.4 years (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 next.

*Study 1 was conducted in the United States and Study 2 in the EU.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

Females who can become pregnant (continued):

- 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.

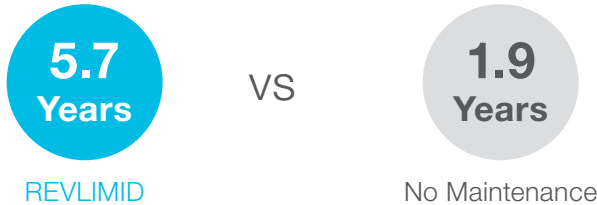
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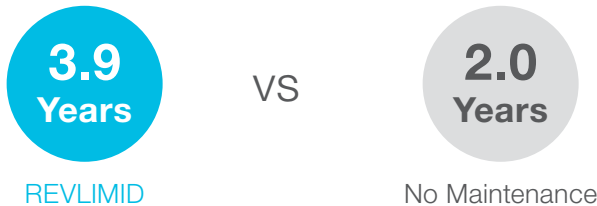
In Study 1, 50% of patients on REVLIMID maintenance lived for 5.7 years without their disease progressing. “Median” means half of the patients had a higher result while half of the patients had a lower result.

Median PFS vs No Maintenance in Study 1.†



In Study 2, patients who took REVLIMID experienced a median PFS of 3.9 years vs 2.0 years with no maintenance treatment.

Median PFS vs No Maintenance in Study 2.†



†Median follow-up of 72.4 months.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

Females who can become pregnant (continued):

- 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.

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

Additional REVLIMID® (lenalidomide) 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 are the OS data from the studies:

OS

In Study 1



Patients who took REVLIMID maintenance therapy lived a median* of 9.3 years

VS



Patients who took no maintenance therapy lived a median* of 7.0 years

*Think of median as the middle value of a set of data points. Study 1 was conducted in the United States. Study 2 was conducted in the EU. Talk to your doctor about what these results may mean to you.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

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 the REMS Call 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, a Bristol-Myers Squibb Company, 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, a Bristol-Myers Squibb Company, at the phone number listed above.

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In Study 2

**8.8
Years**

VS

**7.3
Years**

Patients who took REVLIMID maintenance therapy lived a median* of 8.8 years

Patients who took no maintenance therapy lived a median* of 7.3 years

*Think of median as the middle value of a set of data points. Study 1 was conducted in the United States. Study 2 was conducted in the EU. Talk to your doctor about what these results may mean to you.

Safety Findings

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).

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

REVLIMID can pass into human semen:

- Males, including those who have had a vasectomy, must always use a latex or synthetic condom during any sexual contact with a pregnant female or a female that can become pregnant while taking REVLIMID, during any breaks (interruptions) in your treatment with REVLIMID, and for up to 4 weeks after stopping REVLIMID.
- Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with a female who is or could become pregnant.

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Revlimid[®]
(lenalidomide) capsules
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How REVLIMID® (lenalidomide) works

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**:



Stimulates: Helps your immune system recognize and destroy myeloma cells



Strikes: Targets and kills myeloma cells



Starves: Helps prevent new myeloma cell growth by starving them of blood

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

REVLIMID is the only FDA-approved maintenance therapy recommended by the National Comprehensive Cancer Network® (NCCN®) for multiple myeloma.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

REVLIMID can pass into human semen (continued):

- Do not donate sperm while taking REVLIMID, during any breaks (interruptions) in your treatment, and for up to 4 weeks after stopping REVLIMID. If a female becomes pregnant with your sperm, the baby may be exposed to REVLIMID and may be born with birth defects.

Men: If your female partner becomes pregnant, you should call your healthcare provider right away.

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Revlimid®
(lenalidomide) capsules
2.5 - 5 - 10 - 15 - 20 - 25 mg

How to take REVLIMID maintenance therapy

REVLIMID maintenance therapy is taken by itself, without dexamethasone, as maintenance therapy for patients who have had an auto-HSCT. It's a pill you take once a day, at home or wherever is convenient for you.



REVLIMID maintenance therapy: one 10-mg pill, once daily, no dexamethasone needed

Capsule shown is not actual size

The standard starting dose for most patients is:

- One 10-mg pill, once daily
- Your doctor may adjust your starting dose based on your specific needs
- 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
- This maintenance dosing should continue unless your myeloma gets worse, or if you have side effects that you are unable to tolerate

Be sure to tell your doctor about any side effects that you experience while taking REVLIMID.

How long do I need to be on REVLIMID maintenance therapy?

REVLIMID maintenance therapy is taken continuously, without a break, as a once-daily pill, unless otherwise directed by your doctor. In clinical trials, patients took REVLIMID maintenance therapy every day until their disease progressed, they experienced intolerable side effects, or patient withdrew for another reason.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

- **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.

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Important things to remember when taking REVLIMID® (lenalidomide)



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.



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.

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Side effects

REVLIMID may cause some side effects. For certain side effects, your doctor can adjust your dosage of REVLIMID to help reduce them so you can stay on treatment and receive the benefits of REVLIMID longer.

Serious side effects of REVLIMID include:

- birth defects
- increased risk of death in people with chronic lymphocytic leukemia (CLL)
- risk of new cancers (malignancies)
- severe liver problems (including liver failure and death)
- severe skin reactions and severe allergic reactions
- tumor lysis syndrome (TLS)
- worsening of your tumor (tumor flare reaction)
- thyroid problems
- risk of early death in MCL

The most common side effects of REVLIMID include:

- diarrhea
- fever
- rash
- itching
- nausea
- swelling of the limbs and skin
- constipation
- cough and other cold-like symptoms
- tiredness or weakness

These are not all the possible side effects of REVLIMID. See “What are the possible side effects of REVLIMID?” on pages 22-24 for a comprehensive list and additional information.

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

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2.5 - 5 - 10 - 15 - 20 - 25 mg

Lenalidomide REMS Program

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

Information for men



Counseling

Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. You should be instructed not to extensively handle or open REVLIMID capsules.



Enrollment

You and your healthcare provider will then complete and submit the REVLIMID Patient-Physician Agreement Form.



Complete Mandatory Confidential Survey

You will not have to take a survey for your first prescription, but will have to do so for the following ones. Visit **LenalidomideREMS.com** or call 1-888-423-5436 and press 1 to take the survey.



Prescription

Your healthcare provider will send your prescription to a certified pharmacy.



Pharmacy Call

The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of REVLIMID before you receive your prescription. They will also coordinate delivery of REVLIMID to you.



Receive REVLIMID

REVLIMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment.

For each of your subsequent REVLIMID prescriptions, you will need to follow a similar process. For full, detailed information about the Lenalidomide REMS program requirements, please visit **LenalidomideREMS.com** or review the Patient Guide to Lenalidomide REMS program.

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Information for women



Counseling

Your healthcare provider will counsel you on why and how you and your partner should prevent pregnancy. Your healthcare provider will also inform you not to share the drug, not to donate blood, and about appropriate contraceptive use. You should be instructed not to extensively handle or open REVLIMID capsules.



Pregnancy Test #1

If you can get pregnant, you must take an initial pregnancy test within 10-14 days before getting a REVLIMID prescription.



Pregnancy Test #2

If you can get pregnant, you must take a second pregnancy test within 24 hours before getting a REVLIMID prescription.



Enrollment

You and your healthcare provider will then complete and submit the REVLIMID Patient-Physician Agreement Form.



Complete Mandatory Confidential Survey

You and your healthcare provider will each complete a survey. Visit **LenalidomideREMS.com** or call 1-888-423-5436 and press 1 to take the survey.



Prescription

Your healthcare provider will send your prescription to a certified pharmacy.



Pharmacy Call

The certified pharmacy will contact you to provide counseling on the serious risks and safe-use conditions of REVLIMID before you receive your prescription. They will also coordinate delivery of REVLIMID to you.



Receive REVLIMID

REVLIMID will be shipped with a Medication Guide to the address you provide. A signature will be required to receive this shipment.

For each of your following prescriptions, pregnancy tests will be required depending on your ability to get pregnant. For full, detailed information about the Lenalidomide REMS program requirements, please visit **LenalidomideREMS.com** or review the Patient Guide to Lenalidomide REMS program.

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The importance of monitoring during your treatment

When you take REVLIMID® (lenalidomide) maintenance therapy, you'll need to continue regular monitoring and take certain tests. Your doctor looks for changes from one month to the next.

Common tests include:

- Urine
- Blood
- Bone marrow biopsy
- X-rays or other radiology tests

Women taking REVLIMID will also need to take routine pregnancy tests. Please see the Lenalidomide REMS program details on pages 14-15.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

- **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

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BMS Access Support® Can Provide Patient Access and Reimbursement Assistance

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer BMS Access Support. BMS Access Support provides resources to help patients understand their insurance coverage. In addition, we can share information on sources of financial support, including co-pay assistance for eligible commercially insured patients.



How BMS Access Support May Help

Find out how BMS can work with patients and their healthcare providers to help access a prescribed BMS medication.



Financial Support Options

There may be programs and services that could help with the cost of treatment. Learn about what options are available.



Additional Resources

We provide videos, tools, and other resources that may help with your access and reimbursement needs.

Have Questions About Our Program or Possible Financial Support?

If you have questions about coverage for a prescribed BMS medication, BMS Access Support may be able to help. Patients and their healthcare provider can complete an enrollment form to learn about programs that may be of assistance. Visit our website or contact BMS Access Support to learn more.



Call Bristol Myers Squibb Access Support at
1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday



Visit www.BMSAccessSupport.com

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Frequently Asked Questions (FAQs)

Q: I've just had a transplant. Why would I need more treatment?

A: An SCT is effective in helping MM patients significantly reduce myeloma cells and restore the bone marrow's ability to produce healthy blood cells. But after an SCT, 100 million myeloma cells can remain in your body, even with a complete response. Many doctors recommend maintenance therapy following an SCT because it plays an important part in extending the response from a transplant for as long as possible.

Q: How long will I need to take treatment?

A: In clinical trials, patients took REVLIMID® (lenalidomide) maintenance therapy every day, until their disease progressed or they experienced intolerable side effects. In studies, low white blood cells (neutropenia) and low platelets (thrombocytopenia) were the most common adverse events that led to the discontinuation of REVLIMID maintenance therapy in a small percentage (<3%) of patients.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID? (continued)

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

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2.5 - 5 - 10 - 15 - 20 - 25 mg

Frequently Asked Questions (FAQs) (continued)

Q: What is the right dose for REVLIMID maintenance therapy?

A: The standard dosing for maintenance therapy with REVLIMID® (lenalidomide) is one 10-mg pill, taken once every day by itself (without dexamethasone). If tolerated, your doctor may increase your dose to 15 mg of REVLIMID once daily.

Q: What can I do to manage side effects?

A: Tell your healthcare team immediately about any side effects you are experiencing, and do not stop taking REVLIMID unless directed. Your doctor may adjust your dose to help reduce side effects. In the case of a severe side effect, your doctor may tell you to discontinue treatment.

Q: What should I do if I miss a dose?

A: 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.

Q: How should I store REVLIMID?

A: Store REVLIMID at room temperature between 68°F to 77°F (20°C to 25°C). Return any unused REVLIMID capsules to Celgene or your healthcare provider.

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?”**
- are allergic to lenalidomide or any of the ingredients in REVLIMID. See the Medication Guide for a complete list of ingredients in REVLIMID.

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Frequently Asked Questions (FAQs) (continued)

Q: Why are results from the two clinical trials different?

A: Study 1 and Study 2 were both designed to evaluate the effectiveness and safety of REVLIMID as a maintenance therapy after auto-HSCT, but there were many differences in how the studies were conducted. Some differences between the studies include:

- Study location: Study 1 took place in the United States; Study 2 took place in France, Belgium, and Switzerland.
- Different therapy regimens before transplant (also called induction therapy): Study 1 included the use of REVLIMID-based induction therapy in some patients; Study 2 did not.
- Use of a short course of additional therapy after transplant (also called consolidation therapy): Study 1 did not use consolidation therapy; Study 2 did.

These are not all of the differences between the studies. Talk to your doctor to understand what the study results may mean for you.

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.

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Important Safety Information (continued)

What should I tell my healthcare provider before taking REVLIMID? (continued)

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 Lenalidomide REMS program

- Swallow REVLIMID capsules whole, with water, 1 time a day. **Do not open, break, or chew your capsules.**
- **REVLIMID may be taken with or without food.**
- Take REVLIMID at about the same time each day.
- Do not open or break 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** while taking REVLIMID, during any breaks (interruptions) in your treatment, and for up to 4 weeks after stopping 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.

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

Please see detailed Important Safety Information on pages 2-24, and full [Prescribing Information](#), including Boxed WARNINGS and [Medication Guide](#).



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

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Important Safety Information (continued)

What are the possible side effects of REVLIMID? (continued)

- **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
 - peeling of your skin or blisters
 - severe itching
 - 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)** can happen with REVLIMID and may cause death. Tell your healthcare provider if you get any of these symptoms of tumor flare reaction while taking REVLIMID: tender, swollen lymph nodes; low-grade fever, pain, or rash.

Your healthcare provider may tell you to decrease your dose, temporarily stop or permanently stop taking REVLIMID if you develop certain serious side effects during treatment with REVLIMID.

- **Thyroid problems.** Your healthcare provider may check your thyroid function before you start taking REVLIMID and during treatment with REVLIMID.
- **Risk of early death in MCL.** In people who have Mantle Cell Lymphoma (MCL), there may be a risk of dying sooner (early death) when taking REVLIMID. Talk with your healthcare provider about any concerns and possible risk factors.

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2.5 - 5 - 10 - 15 - 20 - 25 mg

Important Safety Information (continued)

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

Please see full [Prescribing Information](#), including **Boxed WARNINGS** and [Medication Guide](#), for REVLIMID.



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