

# Why POMALYST® (pomalidomide)?

## Ask about POMALYST at relapse

Discuss POMALYST with your doctor at your next appointment. It's proven to help fight multiple myeloma (MM) progression after relapse on REVLIMID® (lenalidomide) and a proteasome inhibitor (PI).



It's **a pill** that offers convenient, once-daily dosing.\*<sup>ll</sup>



It's been used to treat **more than 72,000 patients** with relapsed MM.<sup>†‡</sup>



Pomalidomide (POMALYST) is part of a treatment regimen that's **recommended by the National Comprehensive Cancer Network® (NCCN®)**.<sup>§1</sup>

\*POMALYST is taken in combination with dexamethasone on Days 1-21 of a 28-day cycle.

<sup>†</sup>According to POMALYST Risk Evaluation and Mitigation Strategy (REMS) Program enrollments from February 2013-February 2023.

<sup>‡</sup>POMALYST may not work for everyone. Ask your doctor if POMALYST with dexamethasone is right for you. Individual results may vary.

<sup>§</sup>As part of a combination therapy for appropriate patients after at least one prior therapy including lenalidomide and a PI. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

**Reference: 1.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.3.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed May 10, 2023. To view the most recent and complete version of the guideline, go online to [NCCN.org](http://NCCN.org).

## For more information about relapsed MM and questions to ask your doctor, visit [POMALYST.com](http://POMALYST.com).

### What is POMALYST® (pomalidomide)?

POMALYST is a prescription medicine, taken along with the medicine dexamethasone, used to treat adults with multiple myeloma who have previously received at least 2 medicines to treat multiple myeloma, including a proteasome inhibitor and lenalidomide, and whose disease has become worse during treatment or within 60 days of finishing the last treatment. It is not known if POMALYST is safe and effective in children.

### Important Safety Information

**WARNINGS: Risk to unborn babies, and blood clots.**

Please see additional POMALYST Important Safety Information on pages 2-5, as well as full [Prescribing Information](#), including [Boxed WARNINGS](#) and [Medication Guide](#).

## Important Safety Information (continued)

### What is the most important information I should know about POMALYST® (pomalidomide)?

Before you begin taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS® program. Before prescribing POMALYST, your healthcare provider (HCP) will explain the POMALYST REMS program to you and have you sign the Patient-Physician Agreement Form.

POMALYST can cause serious side effects, including:

- **Possible birth defects (deformed babies) or death of an unborn baby.** Females who are pregnant or plan to become pregnant must not take POMALYST.
    - **POMALYST is similar to the medicine thalidomide (THALOMID®)**, which is known to cause severe life-threatening birth defects. POMALYST has not been tested in pregnant females. POMALYST has harmed unborn animals in animal testing.
    - **Females must not get pregnant:**
      - For at least 4 weeks before starting POMALYST
      - While taking POMALYST
      - During any breaks (interruptions) in your treatment with POMALYST
      - For at least 4 weeks after stopping POMALYST
    - **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 acceptable forms of effective birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in treatment, and for at least 4 weeks after stopping POMALYST.
      - Talk with your healthcare provider to find out about options for acceptable forms of birth control that you may use to prevent pregnancy during and after treatment with POMALYST.
    - **If you become pregnant while taking POMALYST, 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
      - REMS Call Center at 1-888-423-5436
- There is a pregnancy exposure registry that monitors the outcomes of females who take POMALYST during pregnancy, or if their male partner takes POMALYST and they are exposed during pregnancy. You can enroll in this registry by calling the REMS Call Center at the phone number listed above.
- **POMALYST 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 POMALYST, during any breaks (interruptions) in your treatment with POMALYST, and for 4 weeks after stopping POMALYST.

Please see additional POMALYST Important Safety Information throughout, as well as full [Prescribing Information](#), including **Boxed WARNINGS** and [Medication Guide](#).

 **Pomalyst**  
(pomalidomide) capsules  
1 · 2 · 3 · 4 mg

## Important Safety Information (continued)

### What is the most important information I should know about POMALYST® (pomalidomide)? (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 POMALYST, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping POMALYST. If a female becomes pregnant with your sperm, the baby may be exposed to POMALYST and may be born with birth defects.

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

- **Do not donate blood** while you take POMALYST, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping POMALYST. If someone who is pregnant gets your donated blood, her baby may be exposed to POMALYST and may be born with birth defects.
- **Blood clots in your arteries, veins, and lungs, heart attack, and stroke can happen if you take POMALYST.**
  - Most people who take POMALYST will also take a blood thinner medicine to help prevent blood clots.
  - Before taking POMALYST, tell your healthcare provider:
    - If you have had a blood clot in the past.
    - If you have high blood pressure, smoke, or if you have been told you have a high level of fat in your blood (hyperlipidemia).
    - About all the medicines you take. Certain other medicines can also increase your risk for blood clots.

#### **Call your healthcare provider or get medical help right away if you get any of the following during treatment with POMALYST:**

- **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.
- 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 POMALYST:**

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

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## Important Safety Information (continued)

### Who should not take POMALYST® (pomalidomide)?

Do not take POMALYST if you:

- Are pregnant, plan to become pregnant, or become pregnant during treatment with POMALYST. **See “What is the most important information I should know about POMALYST?”**
- Are allergic to pomalidomide or any of the ingredients in POMALYST.

### What should I tell my healthcare provider (HCP) before taking POMALYST?

- If you smoke cigarettes (POMALYST may not work as well in people who smoke), have any other medical conditions, or are breastfeeding. Do not breastfeed during treatment with POMALYST—it is not known if POMALYST passes into breast milk and can harm the baby.
- If you have liver problems
- If you have kidney problems and are receiving hemodialysis treatment
- **Tell your HCP about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. POMALYST and other medicines may affect each other, causing serious side effects. Talk with your HCP before taking any new medicines.

### How should I take POMALYST?

Take POMALYST exactly as prescribed and follow all the instructions of the POMALYST REMS program.

- Swallow POMALYST capsules whole with water 1 time a day. **Do not break, chew, or open capsules.**
- Take POMALYST at the same time each day **with or without food.**
- If you are on hemodialysis, take POMALYST after hemodialysis on hemodialysis days.
- Do not open POMALYST capsules or handle them any more than needed. If you touch a broken POMALYST capsule or the medicine in the capsule, wash the area of your body right away with soap and water.
- If you miss a dose of POMALYST and it has been less than 12 hours since your regular time, take POMALYST 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 POMALYST, call your healthcare provider (HCP) right away.
- **Do not share POMALYST with other people.** It may cause birth defects and other serious problems.

### What are the possible side effects of POMALYST?

- **See “What is the most important information I should know about POMALYST?”**
- **POMALYST can cause serious side effects, including:**
  - **Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia) are common with POMALYST, but can also be serious.** You may need a blood transfusion or certain medicines if your blood counts drop too low. Your blood counts should be checked by your healthcare provider (HCP) weekly for the first 8 weeks of treatment and monthly after that.
  - **Severe liver problems, including liver failure and death.** Your HCP should do blood tests to check your liver function during your treatment with POMALYST. Tell your HCP right away if you develop any of the following symptoms: yellowing of your skin or the white parts 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, or feeling very tired.

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## Important Safety Information (continued)

### What are the possible side effects of POMALYST® (pomalidomide)? (continued)

- **Severe allergic and severe skin reactions** can happen with POMALYST and may cause death.
- **Dizziness and confusion.** Avoid taking other medicines that may cause dizziness and confusion during treatment with POMALYST. Avoid situations that require you to be alert until you know how POMALYST affects you.
- **Nerve damage.** Stop taking POMALYST and call your HCP if you develop numbness, tingling, pain, or a burning sensation in your hands, legs, or feet.
- **New cancers (malignancies).** New cancers, including certain blood cancers (acute myelogenous leukemia or AML) have been seen in people who received POMALYST. Talk with your HCP about your risk.
- **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 HCP may do blood tests to check you for TLS.
- The most common side effects of POMALYST include tiredness and weakness, constipation, nausea, diarrhea, shortness of breath, upper respiratory tract infection, back pain, and fever.
- These are not all the possible side effects of POMALYST. Your HCP may tell you to stop taking POMALYST if you develop certain serious side effects during treatment. Call your HCP for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### Important dosing information

- Take POMALYST exactly as prescribed, and follow all the instructions of the POMALYST REMS® program.
- Swallow POMALYST capsules whole with water 1 time a day. Do not break, chew, or open your capsules.
- POMALYST may be taken with or without food.
- Take POMALYST at about the same time each day.
- If you are on hemodialysis, take POMALYST after hemodialysis, on hemodialysis days.
- Do not open the POMALYST capsules or handle them any more than needed. If you touch a broken POMALYST capsule or the medicine in the capsule, wash the area of your body right away with soap and water.
- If you miss a dose of POMALYST 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 POMALYST, call your healthcare provider right away.
- Do not share POMALYST with other people. It may cause birth defects and other serious problems.

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



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