



Understanding Side Effects

This brochure will help you understand and talk about your side effects with your healthcare team.

POMALYST is only available through a restricted distribution program called POMALYST REMS®.

Please see POMALYST Important Safety Information throughout and on pages 2-13, as well as full [Prescribing Information](#), including Boxed WARNINGS regarding risk to unborn babies and blood clots, and [Medication Guide](#).



“I spoke to my doctor and nurse about my side effects and they were really helpful.”

– Marc, patient with relapsed/refractory MM

WHY IS IT IMPORTANT TO LEARN ABOUT SIDE EFFECTS?

While taking POMALYST® (pomalidomide), you may experience side effects. This guide provides tips and questions for you to discuss with your doctor in the event a side effect occurs. It also has information to help you understand what to expect while taking POMALYST.

Always talk with your healthcare team about any side effects you experience.

Important Safety Information

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.

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

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

Why should I talk to my doctor about side effects?

It's important to tell your healthcare team about the side effects you experience in your treatment journey.

Staying on POMALYST® (pomalidomide) until your disease progresses, or until you experience severe side effects that you cannot tolerate, is also important. Your doctor may adjust your dose or tell you to stop taking POMALYST if you experience serious side effects during treatment.

How long will I be taking POMALYST?

POMALYST with dexamethasone is intended to be used until your relapsed/refractory MM worsens. Your doctor may tell you to stop taking POMALYST if you develop certain serious side effects. Your doctor will also decide how long you should take POMALYST, so be sure to follow instructions on treatment, schedule, and dose.

Important Safety Information (continued)

WARNINGS: Risk to unborn babies, and blood clots.

What is the most important information I should know about POMALYST?

Before you begin taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS® program. For more information, call 1-888-423-5436 or go to www.pomalystrems.com. Before prescribing POMALYST, your healthcare provider (HCP) will explain the POMALYST REMS program to you and have you sign the Patient-Physician Agreement Form.

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



What are the possible side effects?

SERIOUS SIDE EFFECTS OF POMALYST® (pomalidomide) INCLUDE:

- Possible birth defects (deformed babies) or death of an unborn baby
- Blood clots in your arteries, veins, and lungs; heart attack; and stroke
- Low white blood cells, low platelets, and low red blood cells
- Severe liver problems, including liver failure and death
- Severe allergic reactions and severe skin reactions
- Dizziness and confusion
- Nerve damage
- Risk of new cancers (malignancies)
- Tumor lysis syndrome (TLS)

The full details about these serious side effects can be found under “What are the possible side effects of POMALYST?” on pages 12-13 of the Important Safety Information.

Your doctor may tell you to stop taking POMALYST if you develop certain serious side effects.

Important Safety Information (continued)

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

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.

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



THE MOST COMMON SIDE EFFECTS OF POMALYST INCLUDE:

- Low white blood cells
- Low red blood cells
- Tiredness and weakness
- Upper respiratory tract infection
- Low platelets
- Fever
- Shortness of breath
- Diarrhea
- Constipation
- Back pain
- Nausea

Important Safety Information (continued)

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

- **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.

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

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What should I do if I experience side effects?

To help you talk to your doctor about side effects, here are some questions you can ask and tips that may help.

Tiredness and weakness

ASK YOUR DOCTOR:

- Would exercise help me feel less tired?
- Would a change in diet help?
- If I am already taking a medicine that makes me feel tired, will POMALYST® (pomalidomide) make me more tired?

Tip Rest when you are feeling tired.

Constipation

ASK YOUR DOCTOR:

- Should I drink more water or liquids?
- Should I keep track of my bowel movements?
- Are there any medicines that may help?

Tip Work with your doctor to see if an exercise plan is appropriate.

Important Safety Information (continued)

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

- **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

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

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Nausea

ASK YOUR DOCTOR:

- Are there foods I should avoid when I have nausea?
- Are there medicines that may help?

Tip Drink clear liquids. Make sure they're cold and sipped slowly.



POMALYST is available in different doses. Your doctor may adjust your dose for certain side effects.

Important Safety Information (continued)

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

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.
- 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.

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Diarrhea

ASK YOUR DOCTOR:

- How much liquid should I drink each day?
- Are there certain foods I should eat?
- Is there a medicine I can take to help with the diarrhea?

Tip Drink clear liquids like water or broth.
Avoid caffeine and alcohol.

Shortness of breath

ASK YOUR DOCTOR:

- Are there activities I should avoid?
- Are there breathing exercises I can try?

Important Safety Information (continued)

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

- **Do not donate blood** while you take POMALYST® (pomalidomide), 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.

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

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Upper respiratory tract infection

ASK YOUR DOCTOR:

- What are some ways to help soothe my throat?
- Are there medicines that may help?



It's important to always talk with your healthcare team about your side effects.

Important Safety Information (continued)

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

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

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

Back pain

ASK YOUR DOCTOR:

- Can an ice pack or hot water bottle help?
- Are there medicines that may help?

Fever

ASK YOUR DOCTOR:

- Are there any dietary restrictions I should follow?
- Are there medicines that may help?

Tip Drink fluids like water, broth, or juice.

Important Safety Information (continued)

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

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)

Who should not take POMALYST?

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.

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

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Important Safety Information (continued)

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.

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



Important Safety Information (continued)

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

- 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.
 - **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.

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



Important Safety Information (continued)

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

- The most common side effects of POMALYST in people with multiple myeloma 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.

Please see full Prescribing Information, including **Boxed WARNINGS and Medication Guide, for POMALYST.**

Please see Important Safety Information throughout and full Prescribing Information, including **Boxed WARNINGS** and Medication Guide.

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Understanding Side Effects

To learn more about the possible side effects of taking POMALYST® (pomalidomide), visit [POMALYST.com](https://www.pomalyst.com).

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