


Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 15-19.

If multiple myeloma relapses

Keep exploring. Keep fighting.

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

POMALYST is a prescription medicine, taken along with the medicine dexamethasone, used to treat people 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.

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

### Selected Important Safety Information

Some of the serious side effects of POMALYST include:

- Possible birth defects (deformed babies) or death of an unborn baby.
- Blood clots in your arteries, veins, and lungs; heart attack; and stroke.

If multiple myeloma relapses

# Keep striving.

If multiple myeloma (MM) stops responding to REVLIMID® (lenalidomide) and a proteasome inhibitor (PI), it's important to know your options. While your healthcare team is the best source of information, this brochure provides answers to common questions about this potential next step in your treatment journey.



## Why POMALYST?

- POMALYST with dexamethasone is proven to **continue the fight** if multiple myeloma stops responding to REVLIMID and a PI
- POMALYST has immune-modulating qualities **similar to REVLIMID**
- POMALYST is a **\*once-daily capsule**, not an injection or infusion

\*Taken on days 1-21 out of a 28-day cycle. Take POMALYST exactly as prescribed by your doctor.


## Selected Safety Information on Serious Side Effects

Some of the serious side effects of POMALYST include:

- **Possible birth defects (deformed babies) or death of an unborn baby.** Do not take POMALYST if you are pregnant, plan to become pregnant, or become pregnant during treatment with POMALYST.
- **Blood clots in your arteries, veins, and lungs; heart attack; and stroke.**

Learn more at [POMALYST.com](http://POMALYST.com)

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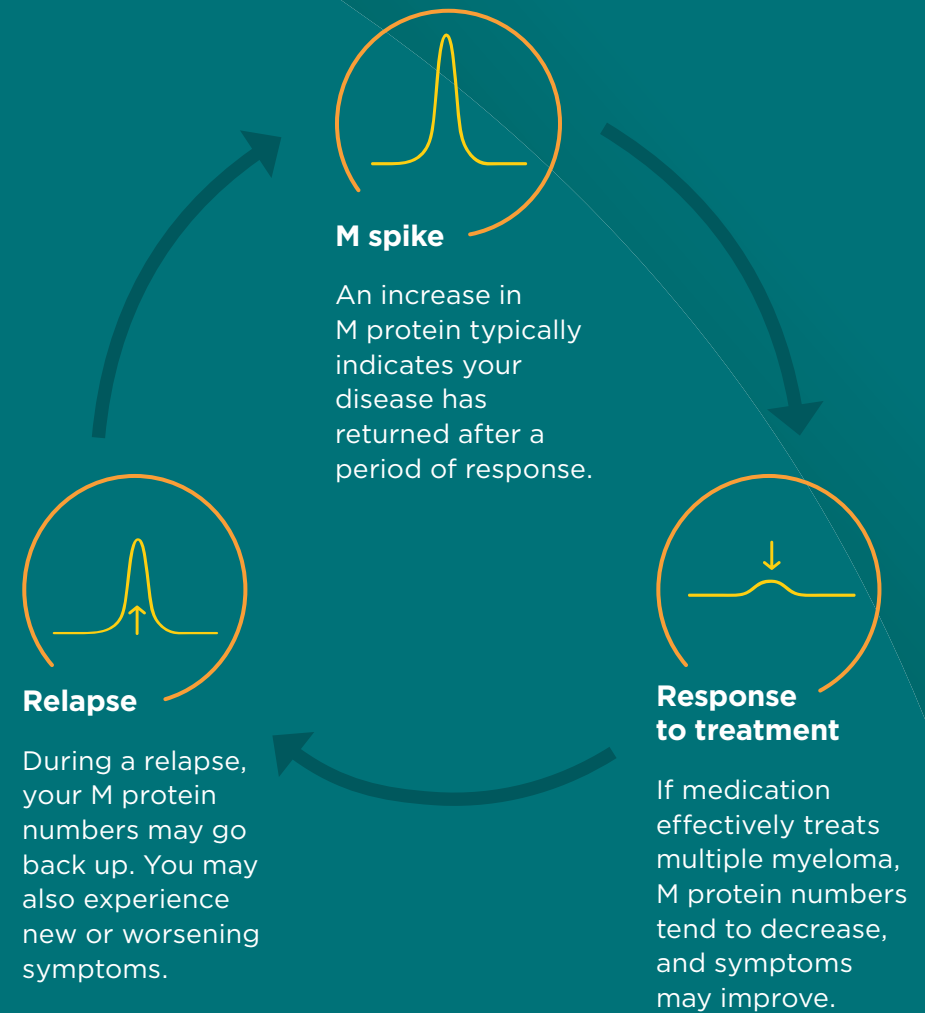
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## Relapsing multiple myeloma is a progressive, cyclical disease

Over time, it's common for a person with multiple myeloma to go through periods of response to treatment and periods of relapse. If MM cells no longer respond to your treatment, your MM is considered "relapsed and/or refractory." That's when your doctor may consider a new treatment.

To find out how your disease is progressing, the levels of M protein in the blood are monitored. A large increase in this protein, or M spike, can indicate a relapse.





# Keep discovering. Keep fighting.



## Selected Safety Information on Serious Side Effects

Some of the serious side effects of POMALYST include:

**-Low white blood cells, low platelets, and low red blood cells are common with POMALYST, but can be serious.**

**-Severe liver problems, including liver failure or death.**

Your healthcare provider may tell you to stop taking POMALYST if you develop certain serious side effects during treatment.

## How POMALYST works

POMALYST has immune-modulating qualities similar to REVLIMID (lenalidomide). However, POMALYST with dexamethasone is proven to **continue the fight** if multiple myeloma stops responding to REVLIMID and a proteasome inhibitor.

Taken in combination with dexamethasone, POMALYST was shown to work in 3 ways in animal models and in vitro\*:



### STRIKE

Targets and kills myeloma cells, even those resistant to REVLIMID



### STIMULATE

Helps enhance the function of certain cells used by the immune system to fight myeloma



### STARVE

Helps reduce new myeloma cell growth by limiting blood supply

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



To learn more about ways it can keep fighting, visit [POMALYST.com/howitworks](https://www.pomalyst.com/howitworks)

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## Proven in a clinical trial

A clinical trial studied 455 patients whose MM had stopped responding to at least 2 prior medicines, including REVLIMID (lenalidomide) and a proteasome inhibitor. A total of 302 patients received POMALYST with low-dose dexamethasone and 153 patients received high-dose dexamethasone alone.

## Selected Safety Information on Serious Side Effects

Some of the serious side effects of POMALYST include:

- **Severe allergic and skin reactions**
- **Dizziness and confusion**
- **Nerve damage**
- **Risk of new cancers (malignancies)**
- **Tumor Lysis Syndrome (TLS)**

Your healthcare provider may tell you to stop taking POMALYST if you develop certain serious side effects during treatment.

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## About the phase 3 clinical trial

To compare treatment effectiveness, the study divided patients into 2 groups. The 1<sup>st</sup> group took POMALYST with low-dose dexamethasone. The 2<sup>nd</sup> group took high-dose dexamethasone alone.

### Median Overall Survival Results

MEDIAN OS WAS  
1.5 TIMES LONGER

#### What Median Overall Survival means

Think of median as the middle value of a set of data points. Overall Survival (OS) measures the amount of time patients were alive following the start of the trial.



#### Study findings

Median OS for patients taking POMALYST with low-dose dexamethasone was 12.4 months, which is about **1.5 times longer** than the 8 months that patients lived when they were given high-dose dexamethasone alone.

### Median Progression-Free Survival Results

MEDIAN PFS WAS  
2 TIMES LONGER

#### What Progression-Free Survival means

Progression-Free Survival (PFS) measures how long a patient lives without the disease getting worse.



#### Study findings

Median PFS for patients taking POMALYST with low-dose dexamethasone was 3.6 months, which is **2 times longer** than the 1.8 months that patients lived without their disease getting worse when they were given high-dose dexamethasone alone.

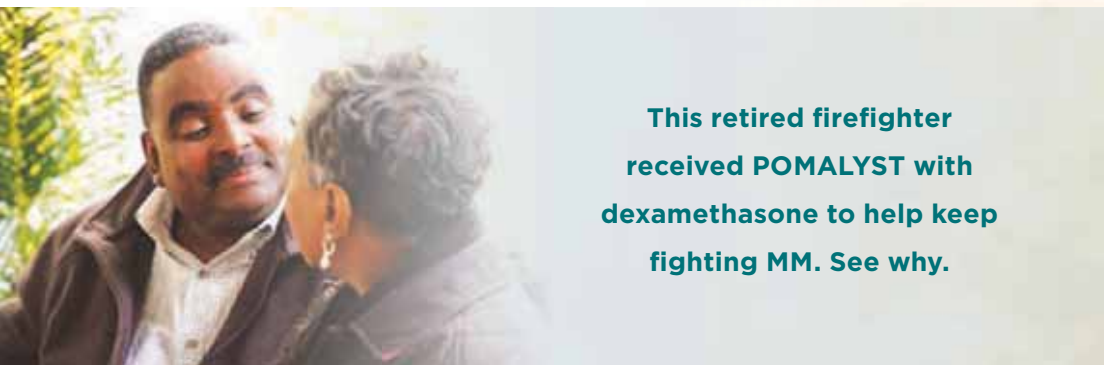
**POMALYST may not work for everyone. Ask your doctor if POMALYST with dexamethasone is right for you.**

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## How POMALYST with dexamethasone worked for Phillip

When Phillip's MM relapsed after taking REVLIMID (lenalidomide) and a proteasome inhibitor, his doctor discussed several treatment options with him, including POMALYST with dexamethasone.



**This retired firefighter received POMALYST with dexamethasone to help keep fighting MM. See why.**



To watch Phillip's video, visit [POMALYST.com/story](https://POMALYST.com/story)

*“My doctor said  
POMALYST  
worked similarly to  
REVLIMID, but that  
it also continues to  
fight the cells that  
become resistant  
to REVLIMID.”*

—Phillip W.

### Selected Safety Information on Common Side Effects

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

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Learn more at [POMALYST.com](https://POMALYST.com)

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## Frequently Asked Questions (FAQs)

### What if I can't afford POMALYST?

If you need help paying for POMALYST, Celgene Patient Support® can help you and your loved ones understand the programs and services that may be available to you. To learn more, see the Financial Support section on page 20 of this brochure.

### What does a “response” to treatment mean?

With MM, a response is an improvement in your myeloma numbers as a result of treatment. There are different levels of response. Response types generally differ by degree of myeloma cell and M protein reduction. Talk to your healthcare team about how response is determined.

### My multiple myeloma has relapsed. What are my next steps?

Your doctor may repeat certain tests to make sure your results are accurate. If your MM has come back, you and your healthcare team will discuss available treatment options and decide on what's best for you.

### How long will I need to be on POMALYST?

POMALYST with dexamethasone is intended to be used until your MM relapses or 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 his or her instructions on treatment, schedule, and dose. **Take POMALYST exactly as prescribed and follow all the instructions of the POMALYST REMS® program.**

### How do I take POMALYST?

POMALYST is a once-daily capsule taken at home or wherever is convenient for you. POMALYST is approved to be taken along with dexamethasone. The suggested starting dose is 4 mg once a day for 21 days out of a 28-day cycle. Make sure to always follow your healthcare team's recommendation for dose and dosing schedule. For more information, please see page 18 of this brochure.

### What are the most common side effects of POMALYST?

You may experience the following common side effects:

- 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

These are not all the possible side effects. Your doctor may also notice other side effects and symptoms that are only evident upon examination or through lab-test results.

### What if I experience side effects?

You may experience side effects while taking POMALYST. Tell your healthcare team about any side effect(s) you experience. Your doctor may adjust or delay your dose, which could help manage some side effects, so you can stay on treatment longer. Your doctor may tell you to stop taking POMALYST if you develop certain serious side effects.

### What should I do if I miss a dose?

If you miss a dose and it has been less than 12 hours since you normally take POMALYST, 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.

### How should I store POMALYST?

Store POMALYST at room temperature 68°F to 77°F (20°C to 25°C). Return any unused POMALYST capsules to Celgene or to your healthcare provider. **Keep POMALYST and all medicines out of the reach of children.**



## POMALYST REMS® Program

Every patient who takes POMALYST® (pomalidomide) must enroll in the POMALYST REMS® program.

### MALES



#### 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 POMALYST® (pomalidomide) capsules



#### Enrollment

You and your healthcare provider will then complete and submit the POMALYST® (pomalidomide) Patient-Physician Agreement Form



#### Complete Mandatory Confidential Survey

You will not have to take a survey for your first prescription, but will have to for the following ones. Visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or call **1-888-423-5436** and press 1 to take your 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 POMALYST before you receive your prescription. They will also coordinate delivery of POMALYST to you



#### Receive POMALYST

POMALYST 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, you will need to follow a similar process. For full detailed information about the POMALYST REMS® program requirements, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or review the Patient Guide to POMALYST REMS® program.

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### FEMALES



#### 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 POMALYST® (pomalidomide) capsules



#### Pregnancy Test #1

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



#### Pregnancy Test #2

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



#### Enrollment

You and your healthcare provider will then complete and submit the POMALYST® (pomalidomide) Patient-Physician Agreement Form



#### Complete Mandatory Confidential Survey

You and your healthcare provider will each complete a survey. Visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or call **1-888-423-5436** and press 1 to take your 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 POMALYST before you receive your prescription. They will also coordinate delivery of POMALYST to you



#### Receive POMALYST

POMALYST 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 POMALYST REMS® program requirements, please visit [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or review the Patient Guide to POMALYST REMS® program.

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## Important Safety Information

### 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. 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, and for at least 4 weeks after stopping POMALYST.
  - Females who can become pregnant:
    - Must have pregnancy tests weekly for 4 weeks once treatment has started, 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 treatment, and for at least 4 weeks after stopping POMALYST. Talk with your HCP to find out about options for acceptable forms of birth control that you may use to prevent pregnancy.

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## 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 HCP.** If your HCP 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 POMALYST during pregnancy, or if their male partner takes POMALYST and they are exposed during pregnancy. You can enroll in this registry by calling Celgene Corporation 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 at least 4 weeks after stopping POMALYST.
  - **If a female becomes pregnant with your sperm, you should call your HCP right away.** The baby may be exposed to POMALYST and may be born with birth defects.
  - Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your HCP if you 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 at least 4 weeks after stopping POMALYST.
- **Do not donate blood** while you take POMALYST, during any breaks (interruptions) in your treatment, and for at least 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.

Learn more at [POMALYST.com](http://POMALYST.com)

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1 · 2 · 3 · 4 mg

## Important Safety Information (continued)

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

- **Blood clots in your arteries, veins, and lungs; heart attack; and stroke. Most people who take POMALYST will also take a blood thinner medicine to help prevent blood clots.**
  - Before taking POMALYST, tell your HCP if you have had a blood clot in the past, if you have high blood pressure or hyperlipidemia (high level of fat in your blood), or if you smoke. Tell your HCP about all the medicines you take because certain other medicines can also increase your risk for blood clots.
  - **Call your HCP or get medical help right away if you get any of the following during treatment with POMALYST: (1) signs or symptoms of a blood clot in the lung, arm, or leg**, including shortness of breath, chest pain, or arm or leg swelling; **(2) signs or symptoms of a heart attack**, including chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen); feeling sweaty; shortness of breath; feeling sick; or vomiting; or **(3) signs or symptoms of stroke**, including 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 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?”

### 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.
- **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.

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## Important Safety Information (continued)

### 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.

Learn more at [POMALYST.com](https://www.pomalyst.com)

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## Important Safety Information (continued)

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

- **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 skin reactions.** Call your HCP if you have any symptoms of an allergic reaction, including: swelling of your lips, mouth, tongue, or throat; trouble breathing; or skin reaction.
- **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, 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.

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## Understand the financial support options that may be available to you

**At Celgene, we believe nothing should come between you and your medicine.** We know paying for treatment can be difficult. Celgene Patient Support® is here to help you and your loved ones understand the financial help that may be available.

**Celgene Patient Support® Specialists are ready to help you and your family with:**



Understanding your insurance plan



Learning about financial assistance that may help you pay for POMALYST



Obtaining information about organizations that may assist you with travel costs to and from your doctor's office

**Enrollment in Celgene Patient Support® is simple:**

Enroll online at [celgenepatientsupport.com](http://celgenepatientsupport.com)

Call us at **1-800-931-8691**,  
Monday – Thursday, 8 AM – 7 PM ET,  
and Friday, 8 AM – 6 PM ET  
(translation services available)

Email us at [patientsupport@celgene.com](mailto:patientsupport@celgene.com)

Learn more at [POMALYST.com](http://POMALYST.com)

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## Start the conversation with your healthcare team

They're the best source of information when it comes to your multiple myeloma treatment.

Here are some questions you may want to ask:

- What are the benefits of POMALYST with dexamethasone?
- How often will I need to take POMALYST with dexamethasone?
- How will I know if it's working?
- What if I experience side effects?
- Are there support programs to help with the cost of POMALYST?
- Is POMALYST approved to be used in combination with other MM treatments?

## Selected Safety Information

Tell your doctor before use if you:

- Are pregnant or planning to become pregnant
- Had a previous blood clot or are at higher risk for a blood clot (eg, high blood pressure, high cholesterol, smoking)
- Smoke cigarettes (POMALYST may not work as well in people who smoke)
- Have any other medical conditions
- Are breastfeeding. **You should not** breastfeed during treatment with POMALYST— it is not known if POMALYST passes into breast milk and can harm the baby
- Are on dialysis
- Have liver problems

**Tell your healthcare provider about all the medicines you take.**

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# Talk to your doctor about POMALYST

For more information, go to [POMALYST.com](http://POMALYST.com)

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

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