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## **Pomalidomide**

pronounced as (poe" ma lid' oh mide)

### **IMPORTANT WARNING:**

Risk of severe, life-threatening birth defects caused by pomalidomide.

For all patients taking pomalidomide:

Pomalidomide must not be taken by patients who are pregnant or who may become pregnant.

There is a high risk that pomalidomide will cause loss of the pregnancy or will cause the baby to be born with birth defects (problems that are present at birth).

A program called Pomalyst REMS<sup>®</sup> has been set up to make sure that pregnant women do not take pomalidomide and that women do not become pregnant while taking pomalidomide. All patients, including women who cannot become pregnant and men, can get pomalidomide only if they are registered with Pomalyst REMS<sup>®</sup>, have a prescription from a doctor who is registered with Pomalyst REMS<sup>®</sup>, and fill the prescription at a pharmacy that is registered with Pomalyst REMS<sup>®</sup>.

You will receive information about the risks of taking pomalidomide and must sign an informed consent sheet stating that you understand this information before you can receive the medication. You will need to see your doctor during your treatment to talk about your condition and the side effects you are experiencing or to have pregnancy tests as recommended by the program.

Tell your doctor if you do not understand everything you were told about pomalidomide and the Pomalyst REMS<sup>®</sup> program and how to use the birth control methods discussed with your doctor, or if you do not think you will be able to keep appointments.

Do not donate blood while you are taking pomalidomide and for 4 weeks after your treatment.

Do not share pomalidomide with anyone else, even someone who has the same symptoms that you have.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with pomalidomide and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website

(<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>  
[<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or  
<http://www.celgeneriskmanagement.com> [<http://www.celgeneriskmanagement.com>] to obtain the Medication Guide.

Talk to your doctor about the risks of taking pomalidomide.

For female patients taking pomalidomide:

If you can become pregnant, you will need to meet certain requirements during your treatment with pomalidomide. You need to meet these requirements even if you have had a tubal ligation ('tubes tied,' surgery to prevent pregnancy). You may be excused from meeting these requirements only if you have not menstruated for 24 months in a row and your doctor says you have passed menopause ('change of life') or you have had surgery to remove your uterus and/or both ovaries. If none of these are true for you, then you must meet the requirements below.

You must use two acceptable forms of birth control for 4 weeks before you begin to take pomalidomide, during your treatment, including at times when your doctor tells you to temporarily stop taking pomalidomide, and for 4 weeks after your treatment. Your doctor will tell you which forms of birth control are acceptable and will give you written information about birth control. You must use these two forms of birth control at all times unless you can promise that you will not have any sexual contact with a male for 4 weeks before your treatment, during your treatment, during any interruptions in your treatment, and for 4 weeks after your treatment.

If you choose to take pomalidomide, it is your responsibility to avoid pregnancy for 4 weeks before, during, and for 4 weeks after your treatment. You must understand that any form of birth control can fail. Therefore, it is very important to decrease the risk of accidental pregnancy by using two forms of birth control. Tell your doctor if you do not understand everything you were told about birth control or you do not think that you will be able to use two forms of birth control at all times.

You must have two negative pregnancy tests before you can begin to take pomalidomide. You will also need to be tested for pregnancy in a laboratory at certain times during your treatment. Your doctor will tell you when and where to have these tests.

Stop taking pomalidomide and call your doctor right away if you think you are pregnant, you miss a menstrual period, or you have sex without using two forms of birth control. If you become pregnant during your treatment or within 30 days after your treatment, your doctor will contact the Pomalyst REMS<sup>®</sup> program, the manufacturer of pomalidomide, and the Food and Drug Administration (FDA).

For male patients taking pomalidomide:

Pomalidomide is present in semen (fluid containing sperm that is released through the penis during orgasm). You must use a latex or synthetic condom, even if you have had a vasectomy (surgery that prevents a man from causing a pregnancy), every time you have sexual contact with a female who is pregnant or able to become pregnant while you are taking pomalidomide and for 28 days after your treatment. Tell your doctor if you have sexual contact with a female without using a condom or if your partner thinks she may be pregnant during your treatment with pomalidomide.

Do not donate sperm while you are taking pomalidomide and for 4 weeks after your treatment.

#### Risk of blood clots:

If you are taking pomalidomide to treat multiple myeloma (a type of cancer of the bone marrow), there is a risk that you will develop a heart attack, a stroke, or a blood clot in your leg (deep vein thrombosis; DVT) that may move through the bloodstream to your lungs (pulmonary embolism, PE). Tell your doctor if you have had a heart attack or a stroke. Your doctor may tell you not to take pomalidomide. Also tell your doctor if you smoke or use tobacco, if you have had a heart attack or a stroke, and if you have or have ever had high blood pressure, or high blood levels of cholesterol or fats. Your doctor may prescribe other medication to be taken along with pomalidomide to decrease this risk. If you experience any of the following symptoms while taking pomalidomide, tell your doctor immediately: severe headache; vomiting; speech problems; dizziness or faintness; sudden complete or partial loss of vision; weakness or numbness of an arm or a leg; chest pain that may spread to the arms, neck, jaw, back, or stomach; shortness of breath; confusion; or pain, swelling, or redness in one leg.

Talk to your doctor about the risks of taking pomalidomide.

## Why is this medication prescribed?

Pomalidomide is used in combination with dexamethasone to treat multiple myeloma (a type of cancer of the bone marrow) that has not improved during or within 60 days of treatment with at least two other medications, including lenalidomide (Revlimid) and a proteasome inhibitor such as bortezomib (Velcade) or carfilzomib (Kyprolis). It is also used to treat Kaposi's sarcoma (a type of cancer that causes abnormal tissue to grow on different parts of the body) related to acquired immunodeficiency syndrome (AIDS) after unsuccessful treatment with other medications or in people with Kaposi's sarcoma who do not have human immunodeficiency virus (HIV) infection. Pomalidomide is in a class of medications called immunomodulatory agents. It works by helping the bone marrow to produce normal blood cells and by killing abnormal cells in the bone marrow.

## How should this medicine be used?

Pomalidomide comes as a capsule to take by mouth. It is usually taken once daily with or without food on days 1 to 21 of a 28-day cycle. This 28-day pattern may be repeated as recommended by your doctor. Take pomalidomide at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take pomalidomide exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with water; do not break or chew them. Do not open the capsules or handle them more than necessary. If your skin comes into contact with broken capsules or powder, wash the exposed area with soap and water. If any capsule contents get in your eyes, wash your eyes right away with water.

Your doctor may need to permanently or temporarily stop your treatment or reduce your dose if you experience certain side effects. Be sure to tell your doctor how you are feeling during your treatment with pomalidomide.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking pomalidomide,

- tell your doctor and pharmacist if you are allergic to pomalidomide, any other medications, or any of the ingredients in pomalidomide capsules. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: carbamazepine (Carbatrol, Tegretol, Teril, others); ciprofloxacin (Cipro); fluvoxamine (Luvox); and ketoconazole (Nizoral). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with pomalidomide, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you are receiving dialysis (medical treatment to clean the blood when the kidneys are not working properly) or have or have ever had liver disease.
- do not breast-feed while you are taking pomalidomide.
- tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this medication.
- you should know that pomalidomide may make you feel dizzy or confused. Do not drive a car, operate machinery, or do other activities that require you to be fully alert until you know how this medication affects you.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

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

Take the missed dose as soon as you remember it. However, if it is less than 12 hours until your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Pomalidomide may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- constipation
- diarrhea

- nausea
- vomiting
- loss of appetite
- weight changes
- uncontrollable shaking of a part of the body
- unusual sweating or night sweats
- anxiety
- dry skin
- swelling of the arms, hands, feet, ankles, or lower legs
- joint, muscle, or back pain
- trouble falling asleep or staying asleep

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, stop taking pomalidomide and call your doctor immediately:**

- rash
- itching
- hives
- blistering and peeling skin
- swelling of the eyes, face, tongue, throat, hands, arms, feet, ankles, or lower legs
- difficulty breathing or swallowing
- hoarseness
- fever, sore throat, chills, cough, or other signs of infection
- yellow eyes or skin
- dark urine
- pain or discomfort in the right upper stomach area
- difficult, frequent, or painful urination
- pale skin
- unusual tiredness or weakness
- unusual bleeding or bruising
- nosebleed
- numbness, burning, or tingling in the hands or feet
- seizures

Pomalidomide may increase the risk that you will develop other cancers. Talk to your doctor about the risks of taking pomalidomide.

Pomalidomide may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Return any medication that is no longer needed to your pharmacy or the manufacturer. Ask your pharmacist if you have any questions about returning your medication.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to pomalidomide.

Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Pomalyst<sup>®</sup>

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