MEDICATION GUIDE
Pomalidomide (poe" ma lid' oh mide)
Capsules

What is the most important information I should know about pomalidomide capsules?
Before you begin taking pomalidomide capsules, you must read and agree to all of the instructions in PS-Pomalidomide REMS. For more information, call 1-888-423-5436 or go to www.PS-PomalidomideREMS.com. Before prescribing pomalidomide capsules, your healthcare provider will explain PS-Pomalidomide REMS to you and have you sign the Patient-Physician Agreement Form.
Pomalidomide capsules can 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 pomalidomide capsules.
  Pomalidomide capsules are similar to the medicine thalidomide (THALOMID). We know thalidomide can cause severe life-threatening birth defects. Pomalidomide capsules have not been tested in pregnant females. Pomalidomide capsules have harmed unborn animals in animal testing.
  Females must not get pregnant:
  - o For at least 4 weeks before starting pomalidomide capsules
  - o While taking pomalidomide capsules
  - o During any breaks (interruptions) in your treatment with pomalidomide capsules
  - o For at least 4 weeks after stopping pomalidomide capsules

  Females who can become pregnant:
  - o 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.
  - o Must agree to use two acceptable forms of 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 pomalidomide capsules.
  - o Talk with your healthcare provider to find out about options for acceptable forms of birth control that you may use to prevent pregnancy before, during, and after treatment with pomalidomide capsules.

  If you become pregnant while taking pomalidomide capsules, 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:
  - o FDA MedWatch at 1-800-FDA-1088, and
  - o REMS Call Center at 1-888-423-5436

  There is a pregnancy exposure registry that monitors the outcomes of females who take pomalidomide capsules during pregnancy, or if their male partner takes pomalidomide capsules and they are exposed during pregnancy. You can enroll in this registry by calling the REMS Call Center at the phone number listed above.
  Pomalidomide can pass into human semen:
  - o 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 pomalidomide capsules, during any breaks (interruptions) in your treatment with pomalidomide capsules, and for 4 weeks after stopping pomalidomide capsules.
  - o 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.
  - o Do not donate sperm while taking pomalidomide capsules, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping pomalidomide capsules. If a female becomes pregnant with your sperm, the baby may be exposed to pomalidomide capsules and may be born with birth defects.

  Men, if your female partner becomes pregnant, you should call your healthcare provider right away.
- **Blood clots in your arteries, veins, and lungs, heart attack, and stroke can happen if you take pomalidomide capsules.**
  Most people who take pomalidomide capsules will also take a blood thinner medicine to help prevent blood clots. Before taking pomalidomide capsules, tell your healthcare provider:
  - o If you have had a blood clot in the past
  - o If you have high blood pressure, smoke, or if you have been told you have a high level of fat in your blood (hyperlipidemia)
  - o 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 pomalidomide capsules:
  - **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.

What is pomalidomide capsules?
Pomalidomide capsules are prescription medicine used to treat adults with:

- **Multiple myeloma.** Pomalidomide capsules are taken along with the medicine dexamethasone, in people who:
  - o have received at least 2 prior medicines to treat multiple myeloma, including a type of medicine known as a proteasome inhibitor and lenalidomide, and
  - o their disease has become worse during treatment or within 60 days of finishing the last treatment.

It is not known if pomalidomide capsules are safe and effective in children.

Who should not take pomalidomide capsules?
Do not take pomalidomide capsules if you:

- are pregnant, plan to become pregnant, or become pregnant during treatment with pomalidomide capsules. **See "What is the most important information I should know about pomalidomide capsules?"**
- are allergic to pomalidomide or any of the ingredients in pomalidomide capsules. **See the end of this Medication Guide for a complete list of ingredients in pomalidomide capsules.**

What should I tell my healthcare provider before taking pomalidomide capsules?
Before you take pomalidomide capsules, tell your healthcare provider if you:

- smoke cigarettes. Pomalidomide capsules may not work as well in people who smoke
- have liver problems
- have kidney problems and are receiving hemodialysis treatment
- have any other medical conditions
- are breastfeeding. **You should not** breastfeed during treatment with pomalidomide capsules. It is not known if pomalidomide passes into your breast milk and can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Pomalidomide capsules 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 pomalidomide capsules?

- Take pomalidomide capsules exactly as prescribed and follow all the instructions of PS-Pomalidomide REMS.
- Swallow pomalidomide capsules whole with water 1 time a day. **Do not break, chew, or open your capsules.**
- **Pomalidomide capsules may be taken with or without food.**
- Take pomalidomide capsules at about the same time each day.
- If you are on hemodialysis, take pomalidomide capsules after hemodialysis, on hemodialysis days.
- Do not open the pomalidomide capsules or handle them any more than needed. If you touch a broken pomalidomide 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 pomalidomide capsules 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 pomalidomide capsules, call your healthcare provider right away.

What should I avoid while taking pomalidomide capsules?

- See "What is the most important information I should know about pomalidomide capsules?"
- **Females: Do not get pregnant and do not breastfeed while taking pomalidomide capsules.**
- **Males: Do not donate sperm.**
- **Do not share pomalidomide capsules with other people**. It may cause birth defects and other serious problems.
- **Do not donate blood** while you take pomalidomide capsules, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping pomalidomide capsules. If someone who is pregnant gets your donated blood, her baby may be exposed to pomalidomide capsules and may be born with birth defects.
- Pomalidomide capsules can cause dizziness and confusion. Avoid taking other medicines that may cause dizziness and confusion during treatment with pomalidomide capsules. Avoid situations that require you to be alert until you know how pomalidomide capsules affect you.

What are the possible side effects of pomalidomide capsules?
Pomalidomide capsules can cause serious side effects, including:

- See "What is the most important information I should know about pomalidomide capsules?"
- **Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia) are common with pomalidomide capsules, 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 weekly for the first 8 weeks of treatment and monthly after that.
- **Severe liver problems, including liver failure and death.** Your healthcare provider should do blood tests to check your liver function during your treatment with pomalidomide capsules. Tell your healthcare provider right away if you develop any of the following symptoms of liver problems:
  - o Yellowing of your skin or the white part of your eyes (jaundice)
  - o Dark or brown (tea-colored) urine
  - o Pain on the upper right side of your stomach area (abdomen)
  - o Bleeding or bruising more easily than normal
  - o Feeling very tired
- **Severe allergic reactions and severe skin reactions** can happen with pomalidomide capsules and may cause death. **Call your healthcare provider if you develop any of the following signs or symptoms during treatment with pomalidomide capsules:**

o a red, itchy, skin rash	o peeling of your skin or blisters	o severe itching
		o fever

Get emergency medical help right away if you develop any of the following signs or symptoms during treatment with pomalidomide capsules:
- o swelling of your lips, mouth, tongue, or throat
- o trouble breathing or swallowing
- o raised red areas on your skin (hives)
- o a very fast heartbeat
- o you feel dizzy or faint

- **Dizziness and confusion. See "What should I avoid while taking Pomalidomide capsules?"**
- **Nerve damage.** Stop taking pomalidomide capsules and call your healthcare provider if you develop symptoms of nerve damage including: numbness, tingling, pain, burning sensation in your hands, legs, or feet.
- **Risk of new cancers (malignancies).** New cancers, including certain blood cancers (acute myelogenous leukemia or AML) have been seen in people who received pomalidomide capsules. Talk with your healthcare provider about your risk of developing new cancers if you take pomalidomide capsules.
- **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.

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

The most common side effects of pomalidomide capsules in people with Multiple Myeloma include:
- o tiredness and weakness
- o constipation
- o nausea
- o diarrhea
- o shortness of breath
- o upper respiratory tract infection
- o back pain
- o fever

These are not all the possible side effects of pomalidomide capsules.

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

How should I store pomalidomide capsules?

- Store pomalidomide capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Return any unused pomalidomide capsules to PS-Pomalidomide REMS by calling 1-888-423-5346 or your healthcare provider.
- Pomalidomide capsules come in a child-resistant package.

Keep pomalidomide capsules and all medicines out of the reach of children.

General information about the safe and effective use of pomalidomide capsules.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take pomalidomide capsules for conditions for which it was not prescribed. Do not give pomalidomide capsules to other people, even if they have the same symptoms you have. It may harm them and may cause birth defects.
If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about pomalidomide capsules that is written for health professionals.
For more information, call 1-888-423-5436 or go to www.PS-PomalidomideREMS.com.

What are the ingredients in pomalidomide capsules?
Active ingredient: pomalidomide
Inactive ingredients: microcrystalline cellulose, maltodextrin, and sodium stearyl fumarate.
The 1 mg capsule shell contains gelatin, titanium dioxide, yellow iron oxide, red iron oxide, and white ink.
The 2 mg capsule shell contains gelatin, titanium dioxide, yellow iron oxide, red iron oxide, and white ink.
The 3 mg capsule shell contains gelatin, titanium dioxide, FD&C blue 2, yellow iron oxide, red iron oxide, and white ink.
The 4 mg capsule shell contains gelatin, titanium dioxide, FD&C blue 2, yellow iron oxide, red iron oxide, and white ink.

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