Pomalidomide (Pomalyst®)

**Pronounced:** POM-ah-list

**Classification:** Immunomodulatory Agent

**About Pomalidomide (Pomalyst®)**

Pomalidomide is a type of "immunomodulatory agent," meaning it works by affecting the immune system. It appears to work in several ways, including inhibiting the formation of blood vessels, which tumors use to get nutrients needed to survive and grow. This is known as anti-angiogenesis. It also interferes with chemicals necessary for the growth of tumors and can cause cell death.

**How to Take Pomalidomide**

Pomalidomide is given in a capsule form. Swallow the capsule whole with water – do not break, crush or chew this medication. Take this medication with or without food. If you miss a dose and it has been less than 12 hours since your regular dose time, take it as soon as you remember. If it has been more than 12 hours, skip the dose. Do not take 2 doses at once to make up for a missed dose. If you are on dialysis, you should take this medication after dialysis treatments. This medication may also be given with a steroid, such as dexamethasone.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

Do not smoke tobacco while taking this medication, as this can reduce the effectiveness of the medication. Be sure your healthcare provider is aware of all the medications and supplements you are taking, as this medication can interact with some other medications including carbemazepine, rifampin, cimetidine, ciprofloxacin, estrogen replacement, oral contraceptives, progestins, fluvoxamine, deferiprone, Echinacea, and tacrolimus. Be sure to tell your health care team about all medications and supplements you take.

**Pomalyst REMS Program**

In order to receive pomalidomide, patients will need to participate in a program called REMS (Risk Evaluation and Mitigation Strategy). This program educates healthcare professionals and patients about the dangers of pomalidomide exposure to a fetus. This exposure can cause serious birth defects and patients taking the medication will need to use two reliable forms of birth control. This includes men taking pomalidomide because it is present in sperm. The REMS program limits who can prescribe and dispense the medication. Patients will also need to complete a survey and safety agreement before starting the drug and every month they are taking it. Important safety reminders:

- Women should not become pregnant for 4 weeks before therapy, during therapy (even if there are breaks or pauses in treatment), or for 4 weeks after therapy is stopped.
- Women who can become pregnant must agree to use 2 forms of reliable birth control during treatment (even if there are breaks or pauses in treatment), and for four weeks after therapy is stopped.
- Men should not father a child for 4 weeks before therapy, during therapy (even if there are breaks or pauses in treatment), or for 4 weeks after therapy is stopped.
- Men must use a condom for any sexual contact during this time, even if they have had a vasectomy with women of childbearing potential and for up to 28 days after stopping treatment.
- Any pregnancy (in women taking the medication OR partners of men who take the medication) should be reported to your
oncology team right away.

- Do not donate blood or sperm during therapy and for 4 weeks after stopping therapy.
- A negative pregnancy test 10 to 14 days prior to treatment, within 24 hours prior to treatment, weekly during the first 4 weeks, and every 4 weeks thereafter is required for women of childbearing potential
- Treatment must be stopped immediately for a missed period, abnormal pregnancy test, or abnormal menstrual bleeding; refer to a reproductive toxicity specialist if pregnancy occurs during treatment

**Storage and Handling**

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

**Where do I get this medication?**

Pomalidomide is available only through providers and pharmacies certified by the Pomalyst REMS program. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

**Insurance Information**

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

**Possible Side Effects of Pomalidomide**

There are a number of things you can do to manage the side effects of pomalidomide. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Blood Clots, Stroke and Heart Attack**

Pomalidomide can increase the risk of blood clots, stroke and heart attack. Symptoms can include: swelling, redness or pain in an extremity, chest pain or pressure, pain in your arm, back, neck or jaw, shortness of breath, numbness or weakness on one side of the body, trouble talking, confusion or mental status changes. If you experience any of these symptoms, you should contact your oncology care team immediately or go to an emergency room.

**Fatigue**

*Fatigue* is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Low White Blood Cell Count (Leukopenia or Neutropenia) and Infection**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.
Tips to preventing infection:

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Diarrhea**

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Back Pain, Muscle Spasms or Joint Pain/Aches and Headache**

Your healthcare provider can recommend medications and other strategies to help relieve pain and spasms.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**Peripheral Edema**
Peripheral edema is swelling of the extremities caused by retention of fluid. It can cause swelling of the hands, arms, legs, ankles and feet. The swelling can become uncomfortable. Notify your oncology care team if you are experiencing any new or worsening swelling.

**Fever**
Fever can be a side effect of this medication. Contact your care provider for a temperature of 100.4 °F or 38 °C or greater.

**Decrease in Appetite**
Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Dizziness & Confusion**
In clinical trials with this medication, some patients experienced dizziness and confusion. Do not operate a vehicle or machinery until you know how this medication affects you. Do not combine this medication with other medications that can cause dizziness and confusion. Do not drink alcohol while taking this medication.

**Peripheral Neuropathy (Numbness or Tingling in the Hands and/or Feet)**
Peripheral neuropathy is a toxicity that affects the nerves. It causes numbness or a tingling feeling in the hands and/or feet, often in the pattern of a stocking or glove. This can get progressively worse with additional doses of the medication. In some people, the symptoms slowly resolve after the medication is stopped, but for some it never goes away completely. You should let oncology care team know if you experience numbness or tingling in the hands and/or feet, as they may need to adjust the doses of your medication.

**Rash/Skin Reactions**
Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

Stevens Johnson Syndrome is a rare, but serious, allergic reaction that affects the skin and mucous membranes. It typically starts as a rash or painful blisters and can progress to serious damage to the skin and in some cases, death. It is important that you report any rash to your oncology care team immediately.

**Less common, but important side effects can include:**

- **Secondary Malignancies:** There is a low risk of developing leukemia or other type of cancer due to treatment with this medication, which can occur many years after treatment. This is most often associated with repeated treatments or high doses. Your oncology care team will provide instructions on how to best follow up and be monitored for this.
- **Liver Toxicity:** This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears
dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

- **Tumor Lysis Syndrome:** If there are a large number of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

**Reproductive Concerns**

As discussed above, exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Women should not become pregnant for four weeks prior to starting treatment, during treatment (even if there are breaks or pauses in treatment) or for four weeks after treatment is complete. A woman should use two forms of birth control during this time period. Men should not father a child during treatment (even if there are breaks or pauses in treatment) or for four weeks after treatment is complete. A man should use a condom during sexual contact during this time period even if he has had a vasectomy. Report pregnancy if suspected to your provider immediately. Do not breastfeed while taking this medication.

**Blood & Sperm Donation**

You should not donate blood for 1 month following the last dose of this medication, as it could be given to a pregnant female. Men should not donate sperm during treatment (even if there are breaks or pauses in treatment) and for 4 weeks after stopping pomalidomide.