

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr **POMALYST**[®]
pomalidomide capsules

Read this carefully before you start taking **POMALYST** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **POMALYST**.

POMALYST can only be given to patients who are registered in and meet all conditions of the RevAid[®] program. RevAid[®] is a controlled distribution program of **POMALYST**.

Serious Warnings and Precautions

POMALYST should only be prescribed by a doctor experienced in the use of anti-cancer drugs and registered with the RevAid[®] controlled distribution program.

Serious side effects may occur with the use of POMALYST and could include:

- **birth defects (deformed babies) or death of an unborn baby and spontaneous abortion**
- **decrease in the production of blood cells resulting in very low levels of white blood cells (neutropenia) and of platelets (thrombocytopenia)**
- **infections, which can be life-threatening**
- **blood clots in the veins (Deep Vein Thrombosis) and in the lung (Pulmonary Embolism)**
- **liver problems. Treatment with POMALYST may lead to a higher risk of liver problems which may cause death**
- **severe allergic reaction called anaphylaxis**
- **reactivation of Hepatitis B.** This is when a previous viral infection of the liver becomes active again. This can be life threatening.
- **severe skin reactions, which can be life threatening.** These can include Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS).
- **tumor lysis syndrome.** This is caused by the fast breakdown of cancer cells. When this happens they release their contents, leading to higher or lower levels of certain other chemicals in your blood.
- **POMALYST is only available under a controlled distribution program called RevAid[®].**

What is POMALYST used for?

POMALYST is used to treat adults with multiple myeloma. This is a cancer of plasma cells (a type of white blood cell found in the bone marrow).

POMALYST is either used with

- dexamethasone and bortezomib for patients who:
 - have already had at least one prior treatment regimen including lenalidomide, and
 - had their disease worsen on their last treatment.

Or

- dexamethasone for patients whose disease has gotten worse after at least two other treatments including lenalidomide and bortezomib.

How does POMALYST work?

POMALYST works in the bone marrow. It stimulates the immune system to attack the growth of cancerous myeloma cells. POMALYST can also slow down the growth of cancer cells.

POMALYST when used with dexamethasone and/or bortezomib can stop multiple myeloma from getting worse.

What are the ingredients in POMALYST?

Medicinal ingredients: pomalidomide

Non-medicinal ingredients: FD&C blue #1 (4 mg capsule only), FD&C blue #2, FD&C red #3 (2 mg capsule only), gelatin, pregelatinized starch, mannitol, sodium stearyl fumarate, titanium dioxide, yellow iron oxide (1 mg, 2 mg and 3 mg capsule only)

POMALYST comes in the following dosage forms:

Capsules: 1 mg, 2 mg, 3 mg, or 4mg

Do not use POMALYST if:

- You are pregnant
- You are at risk of becoming pregnant
- You become pregnant during POMALYST treatment
- You are breastfeeding
- You are a male patient and are unable to follow or comply with the contraceptive measures of the RevAid® Program
- You are allergic to pomalidomide, lenalidomide or thalidomide or any of the other ingredients in POMALYST

Female patients who can get pregnant should not take POMALYST unless all conditions of the RevAid® program are met.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take POMALYST. Talk about any health conditions or problems you may have, including if you:

- are pregnant or are planning to get pregnant
- are breastfeeding
- have blood problems
- have or have had heart problems (heart attack or an irregular heartbeat)
- smoke, have high blood pressure or high cholesterol levels
- have had previous hepatitis B infection-
- have liver problems

Other warnings you should know about:

POMALYST may cause birth defects. In order to take this drug you must meet the following conditions:

1. Females who can get pregnant:

- Discuss birth control with your healthcare professional.
- Use at least two effective methods of birth control at the same time.
- Use these two effective methods of birth control:
 - For at least 4 weeks before starting POMALYST treatment
 - During interruptions of POMALYST treatment
 - During POMALYST treatment
 - For at least 4 weeks after stopping POMALYST treatment
- You must have two negative pregnancy tests before starting treatment:
 - The first 7-14 days prior to starting treatment
 - The second within 24 hours of starting treatment.
- You must have negative pregnancy tests during treatment:
 - Once weekly for the first 4 weeks
 - Once every 4 weeks (or once every 2 weeks if your period is irregular) for the duration of treatment and during treatment interruption
- You must have a final pregnancy test 4 weeks after stopping POMALYST.

Any method of birth control can fail. Contact your doctor immediately if you think you may be pregnant. Be sure to also contact your doctor if you miss your period or experience unusual menstrual bleeding.

2. Males:

- POMALYST is present in the sperm of males who take this drug. Use a condom every time you have sexual intercourse with a woman who is pregnant or can get pregnant. This must be done even if you have undergone a successful vasectomy. The condom must be used while:
 - You are taking POMALYST
 - During interruptions of treatment
 - For 4 weeks after stopping POMALYST
- Do not donate sperm while taking POMALYST and for 4 weeks after stopping POMALYST.

- Inform your sexual partner who can get pregnant that:
 - You are taking POMALYST
 - There is a risk of birth defects, stillbirths, and spontaneous abortions if a fetus is exposed to your sperm
 - You must use a condom

Contact your doctor immediately if you think your female partner becomes pregnant while you are taking POMALYST.

3. All Patients:

- Do not give blood while you take POMALYST and for at least 4 weeks after stopping POMALYST
- Do not share POMALYST with other people
- Do not take POMALYST if you are not enrolled in or do not meet the requirements of the RevAid® controlled distribution program

POMALYST is not recommended for use in children under 18 years of age.

Driving and using machines: Before you perform tasks that may require special attention, wait until you know how you respond to POMALYST. POMALYST may cause confusion, fatigue, depressed level of consciousness, and dizziness. If you feel dizzy or tired, do not drive or use tools or machines.

Risk of Other Cancers: During treatment with pomalidomide (the medicinal ingredient in POMALYST), some other cancers have been reported. Your healthcare professional will monitor you for the signs of some cancers.

Blood Tests: You will have blood tests before starting treatment with POMALYST and regular blood tests during your treatment. Your blood will be tested once every week during your first 8 weeks of treatment, and at least monthly after that. Your healthcare professional may adjust your dose of POMALYST or interrupt your treatment based on the results of these tests and on how you are feeling.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. It is possible that POMALYST and other medicines may affect each other causing serious side effects.

The following may interact with POMALYST:

- Fluvoxamine, a drug used to treat depression and obsessive-compulsive disorder (OCD)
- Hormonal Replacement Therapy
- Hormonal Birth Control (estrogens and progestins)

Smoking can make treatment with POMALYST less effective.

How to take POMALYST:

- Take POMALYST exactly as prescribed.

- Swallow capsules whole with water once a day. Take your dose at about the same time each day.
- Do not break, chew, or open your capsules.
- If you have kidney problems and are receiving hemodialysis, take your POMALYST after hemodialysis, on hemodialysis days.
- Females who could become pregnant, or who plan to become pregnant must only handle POMALYST capsules if they are wearing latex gloves. This is important to remember for anyone helping you with your medication.

Usual adult dose:

Starting dose for POMALYST in combination with dexamethasone and bortezomib: 4 mg by mouth, once per day on days 1-14 of each 21 day cycle.

Starting dose for POMALYST in combination with dexamethasone alone: 4 mg by mouth, once per day on days 1-21 of each 28 day cycle.

Your starting dose of POMALYST may be different. This will happen if you:

- have liver problems; or
- have kidney problems and are receiving hemodialysis; or
- are taking certain medicines.

Your doctor may change your dose during treatment. Your doctor will also decide how long you need to take POMALYST. It will depend on your response to the treatment.

Overdose:

If you think you have taken too much POMALYST, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If less than 12 hours have passed since missing a dose, take the dose. If more than 12 hours have passed since missing a dose at the normal time, do not take the dose. Take the next dose at the normal time on the following day. Do not take 2 doses at the same time.

What are possible side effects from using POMALYST?

These are not all the possible side effects you may feel when taking POMALYST. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- tiredness
- rash, itching
- fever
- flu (influenza), nose, throat and sinus infections
- swelling of arms or legs
- changes in taste (dysgeusia)
- inflammation of mouth and lips (stomatitis)
- diarrhea, nausea, constipation, vomiting, loss of appetite, indigestion (dyspepsia), bloating (abdominal distension)

- weight loss
- abdominal pain, pelvic pain, back pain, chest pain, muscle spasm
- falls
- difficulty breathing / breathlessness (dyspnea)
- cough
- dizziness
- headache
- tremor
- difficulty sleeping

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Peripheral neuropathy: numbness or tingling in feet or hands		✓	
Neutropenia, neutropenic sepsis, leukopenia, lymphopenia (low levels of white blood cells): chills, fever, sweating, any signs of infection		✓	
Anemia (low levels of red blood cells): fatigue, pale skin, shortness of breath, weakness		✓	
Thrombocytopenia (low levels of platelets in the blood): bleeding from the gums or other sites, or abnormal bleeding, bruising		✓	
Infections including chest infections, pneumonia, bronchitis, bronchial pneumonia: fever, chills, fatigue, cough, shortness of breath, coughing up thick yellow or green mucous, fast heartbeat; urinary tract infection: frequent urination, burning or painful urination, cloudy urine		✓	
COMMON			
Bone pain	✓		
Venous thromboembolism including deep vein thrombosis (blood clot in a blood vessel): pain with arm or leg swelling and redness; pulmonary embolism (blood clot in the lungs): shortness of breath, sudden chest pain or difficulty breathing			✓
Confusion		✓	
Urinary retention: difficulty urinating	✓		

Depressed level of consciousness: altered mental state			✓
Vertigo: dizziness, spinning sensation	✓		
Cataract: clouding of the lens of the eye, blurry or dim vision, eye pain		✓	
Depression: feeling sad		✓	
Kidney failure: lack of urine, shortness of breath, confusion			✓
Hypotension (low blood pressure): lightheadedness, dizziness or fainting		✓	
Hypertension (high blood pressure): headache, shortness of breath		✓	
RARE			
Tumor lysis syndrome (the sudden, rapid death of cancer cells due to treatment): nausea, shortness of breath, irregular heartbeat, lack of urine, cloudy urine, severe muscle weakness, seizures			✓
Allergic reactions (anaphylactic reactions, angioedema, urticaria): rapid swelling of the face, lips, tongue and throat; breathing or swallowing problems, red itchy welts on skin			✓
Severe dermatologic reactions including Stevens-Johnson Syndrome or toxic epidermal necrolysis (rare skin reactions): peeling or blistered skin, changes in the appearance of your skin			✓
Hepatitis / reactivation of hepatitis (inflammation of the liver): itchy skin, yellowing of skin and whites of eyes, pale coloured stools, dark coloured urine, abdominal pain			✓
Lung disease or lung inflammation (pneumonitis): shortness of breath, dry cough, fatigue			✓
VERY RARE			
Basal and squamous cell carcinoma (certain types of skin cancer): changes in the appearance of your skin or growths on your skin			✓
UNKNOWN			

Drug reaction with eosinophilia and systemic symptoms (DRESS; rare reaction to some medicines): flu-like symptoms, rash on the face which may extend all over the body, fever			✓
Symptoms of Progressive Multifocal Leukoencephalopathy: vision changes, difficulty speaking, weakness in limbs, change in the way you walk or balance, persistent numbness, decreased or loss of sensation, memory loss or confusion			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store POMALYST at 15-30°C.

Keep out of the reach and sight of children.

If you want more information about POMALYST:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website www.bms.com/ca/en; the website www.RevAid.ca, or by contacting the sponsor, Bristol-Myers Squibb Canada, at: 1-888-RevAid1 (1-888-738-2431).

This leaflet was prepared by Bristol-Myers Squibb Canada, Montreal, Canada H4S 0A4

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