

## PART III: CONSUMER INFORMATION

### Pr POMALYST® pomalidomide

This leaflet is part III of a three-part "Product Monograph" published when POMALYST® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about POMALYST®. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

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®.

#### What the medication is 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.

#### What it does:

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.

#### When it should not be used:

Do not take 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.**

#### What the medicinal ingredient is:

Pomalidomide

#### What the nonmedicinal ingredients are:

Each capsule contains mannitol, pregelatinized starch, and sodium stearyl fumarate. The additional composition of the different capsule strengths is provided in the table below.

Strength	Imprint	Composition	Colour	Package size
1 mg	POML 1 mg	Gelatin, titanium dioxide, FD&C blue #2, yellow iron oxide	Dark blue opaque and yellow opaque	21 count blisters
2 mg	POML 2 mg	Gelatin, titanium dioxide, FD&C blue #2, yellow iron oxide, FD&C red #3	Dark blue opaque and orange opaque	21 count blisters
3 mg	POML 3 mg	Gelatin, titanium dioxide, FD&C blue #2, yellow iron oxide	Dark blue opaque and green opaque	21 count blisters
4 mg	POML 4 mg	Gelatin, titanium dioxide, FD&C blue #1, FD&C blue #2	Dark blue opaque and blue opaque	21 count blisters

#### What dosage forms it comes in:

Capsules. Each capsule contains 1 mg, 2 mg, 3 mg, or 4 mg of pomalidomide.

## WARNINGS AND PRECAUTIONS

### 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®.**

**BEFORE you use POMALYST® talk to your doctor or pharmacist 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 ever had an allergic reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called ‘thalidomide’ or ‘lenalidomide’
- have had previous hepatitis B infection.

During treatment with pomalidomide (the active ingredient in POMALYST®), some other cancers have been reported. Your healthcare professional will monitor you for the signs of some cancers.

**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 health care provider.
- 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®. If you feel dizzy or tired, do not drive or use tools or machines.

## INTERACTIONS WITH THIS MEDICATION

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. It is possible that POMALYST® and other medicines may affect each other causing serious side effects.

Drugs that may interact with POMALYST® include: fluvoxamine, Hormonal Replacement Therapy, and Hormonal Contraception (estrogens and progestins).

POMALYST® may cause confusion, fatigue, depressed level of consciousness, and dizziness. Do not drive or operate machinery until you know how POMALYST® affects you.

Smoking can make treatment with POMALYST® less effective.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

## PROPER USE OF THIS MEDICATION

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.

### Usual 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 the total duration of therapy that you need. It will depend on your response to the treatment.

Females who could become pregnant, or who plan to become pregnant must handle POMALYST® capsules if they are using latex gloves. This is important to remember for anyone helping you with your medication.

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

**Overdose:**

In case of drug overdose, contact a health care practitioner, 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.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, POMALYST® can have side effects. These are not all the possible side effects that may be experienced when taking POMALYST. If any side effects not listed here are experienced, or these bother you or do not go away, tell 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

POMALYST can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	<b>Urinary retention:</b> difficulty urinating	✓		
	<b>Depressed level of consciousness:</b> altered mental state			✓
	<b>Vertigo:</b> dizziness, spinning sensation	✓		
	<b>Cataract:</b> clouding of the lens of the eye, blurry or dim vision, eye pain		✓	
	<b>Depression:</b> feeling sad		✓	
	<b>Kidney failure:</b> lack of urine, shortness of breath, confusion			✓
	<b>Hypotension (low blood pressure):</b> lightheadedness, dizziness or fainting		✓	
	<b>Hypertension (high blood pressure):</b> headache, shortness of breath		✓	
Rare	<b>Tumor lysis syndrome</b> (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			✓
	<b>Allergic reactions (anaphylactic reactions, angioedema, urticaria):</b> rapid swelling of the face, lips, tongue and throat; breathing or swallowing problems, red itchy welts on skin			✓
	<b>Severe dermatologic reactions including Stevens-Johnson Syndrome or toxic epidermal necrolysis (rare skin reactions):</b> peeling or blistered skin, changes in the appearance of your skin			✓
	<b>Hepatitis / reactivation of hepatitis (inflammation of the liver):</b> itchy skin, yellowing of skin and whites of eyes, pale coloured stools, dark coloured urine, abdominal pain			✓
	<b>Lung disease or lung inflammation (pneumonitis):</b> shortness of breath, dry cough, fatigue			✓

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Rare	<b>Basal and squamous cell carcinoma</b> (certain types of skin cancer): changes in the appearance of your skin or growths on your skin			✓
Unknown	<b>Drug reaction with eosinophilia and systemic symptoms</b> (DRESS; rare reaction to some medicines): flu-like symptoms, rash on the face which may extend all over the body, fever			✓

This is not a complete list of side effects. If you have any unexpected effects after receiving POMALYST®, ask your doctor or pharmacist.

### HOW TO STORE IT

Store POMALYST® at 15-30°C. Keep out of the reach and sight of children.

### REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 1908C  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

## **MORE INFORMATION**

The information in this document is current as of the last revision date shown below. The most current information can be found at: [www.RevAid.ca](http://www.RevAid.ca) or by contacting the sponsor, Celgene, at: 1-888-RevAid1 (1-888-738-2431) or visiting [www.celgenecanada.net](http://www.celgenecanada.net).

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