

## 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 with dexamethasone to treat patients with multiple myeloma who have already had at least two prior treatment regimens and who have failed on the medications bortezomib and lenalidomide, with their disease becoming worse on the last regimen.

#### **What it does:**

POMALYST® works in multiple ways within the bone marrow to slow down the growth of cancerous myeloma cells.

#### **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)**
- **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**

**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)
- 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.

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

#### 1. Females who can get pregnant:

- Discuss contraception (birth control) with your health care provider.
- Use at least two effective methods of contraception at the same time.

- Use these two effective methods of contraception:
  - 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. You should contact your doctor immediately if you think you may be pregnant. You should 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.

**You should 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.

### 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

#### Usual dose:

Starting dose: 4 mg daily on days 1-21 of 28 day cycles in combination with dexamethasone. The starting dose of POMALYST® may be adjusted if you have liver problems or kidney problems and are receiving hemodialysis.

Your doctor may change the dosage during treatment, and will decide the total duration of therapy that you need. It all depends on your response to the treatment.

Take POMALYST® exactly as prescribed.

Swallow POMALYST® capsules whole with water once a day. You should try to take it 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 POMALYST® following hemodialysis, on hemodialysis days.

It is important to remember that if you are being assisted with your medication, females who could become pregnant, or who plan to become pregnant can handle POMALYST® capsules if they are using latex gloves.

You will have regular blood tests during your treatment with POMALYST®. You should have your blood 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 your blood tests and on your general condition.

#### 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. The following are the most commonly reported side effects (≥10%):

**Very Common:** anemia (decrease in red blood cells), neutropenia (decrease in white blood cells), thrombocytopenia (decrease in platelets that help with blood clotting), leucopenia (decrease in white blood cells), tiredness, fever, swelling of arms or legs, pneumonia, constipation, diarrhea, nausea, back pain, bone pain, muscle spasm, difficulty breathing / breathlessness, cough, loss of appetite, “pins and needles” in hands and feet

The following are commonly reported side effects (≥1% and <10%):

**Common:** fever / neutropenia (decrease in white blood cells), nose, throat and sinus infections, chest infections, bronchitis, bronchial pneumonia (a type of pneumonia), urinary tract infection, neutropenic sepsis (a serious blood infection), vomiting, pulmonary embolism (blood clot in or around the lungs), dizziness, headache, tremor, depressed level of consciousness (altered mental state), hyperkalemia (increase in potassium levels in blood, which can cause abnormal heart rhythm), hyponatremia (decrease in sodium levels in blood), itching, rash, difficulty sleeping, confusion, kidney failure, difficulty urinating, vertigo (spinning sensation), pelvic pain, deep vein thrombosis (blood clots that form in your blood vessels)

Tell your doctor or pharmacist if you experience a side effect which is not listed above or any of the listed side effects that bother you or do not go away.

**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	
Common	Fever / Neutropenia (decrease in white blood cells)		✓	
Common	Tiredness / Anemia (decrease in red blood cells). Fatigue		✓	
Common	Bleeding from the gums or other sites or abnormal bleeding / Thrombocytopenia (decrease in platelets that help with blood clotting)		✓	
Common	Itching	✓		
Common	Chest or other infections / Pneumonia, various infections		✓	
Common	Vomiting	✓		
Common	Bone pain	✓		
Common	Shortness of breath, sudden chest pain or difficulty breathing (which may be symptoms of blood clots in the lungs called pulmonary embolism)			✓
Common	Confusion		✓	
Common	Difficulty urinating	✓		
Rare	Loose or frequent bowel movements / Diarrhea	✓		

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Constipation	✓		
Rare	Nausea		✓	
Rare	Cough	✓		
Rare	Altered mental state / Depressed level of consciousness			✓
Rare	Vertigo (spinning sensation)	✓		
Rare	Arm pain with arm or leg swelling / Deep vein thrombosis (blood clots that form in your blood vessels)			✓
Rare	Symptoms of tumor lysis syndrome: lack of urination, severe muscle weakness, heart rhythm disturbances, and seizures			✓
Rare	Symptoms of allergic reactions (anaphylactic reactions, angioedema, urticaria), such as rapid swelling of the face, lips, tongue and throat; breathing or swallowing problems, red itchy welts on skin			✓
Rare	Peeling skin or blistered skin (Stevens-Johnson Syndrome or toxic epidermal necrolysis). Changes in the appearance of your skin or growths on your skin (certain types of cancer).			✓
Rare	Symptoms of inflammation of the liver (hepatitis/recurrence of hepatitis): itchy skin, yellowing of skin and whites of eyes, pale coloured stools, dark coloured urine, abdominal pain.			✓
Rare	Symptoms of lung tissue disease / lung inflammation (pneumonitis): shortness of breath, dry cough, fatigue, loss of appetite, unintentional weight loss			✓

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	Flu-like symptoms and a rash on the face then an extended rash with a high temperature and swollen glands. (Drug reaction with eosinophilia and systemic symptoms [DRESS])			√

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 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 [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- 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 0701D  
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 [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*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 data 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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