

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrXPOVIO®

selinexor tablets

Read this carefully before you start taking **XPOVIO** 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 **XPOVIO**.

Your cancer will be treated with XPOVIO in combination with the medicines bortezomib and dexamethasone. Read the leaflets for these medications as well as this one.

What is XPOVIO used for?

XPOVIO is used together with bortezomib and dexamethasone to treat adults with multiple myeloma. You will likely already have received at least one treatment for your cancer.

How does XPOVIO work?

XPOVIO is a XPO1 inhibitor cancer medicine. It blocks the action of a substance called XPO1. XPO1 acts inside cells. It is responsible for carrying important materials into and out of the core of the cell (the nucleus). Some of these materials are responsible for cancer cell growth. By blocking XPO1, XPOVIO can slow down the growth of cancer cells, cause cancer cell death and can stop multiple myeloma from getting worse.

What are the ingredients in XPOVIO?

Medicinal ingredients: selinexor

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #2/Indigo Carmine Aluminum Lake, FD&C Blue #1 Brilliant Blue FCF Aluminum Lake, glycerol monostearate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol-partially hydrolyzed, polyvinylpyrrolidone, sodium lauryl sulfate, talc, titanium dioxide.

XPOVIO comes in the following dosage forms:

Tablets, 20 mg

Do not use XPOVIO if:

- you are allergic to selinexor or any of the other ingredients in XPOVIO.

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

- have liver problems
- have eye problems, such as cataracts

Other warnings you should know about:

Female patients – Pregnancy and breastfeeding:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- Avoid getting pregnant while taking XPOVIO. It may harm your unborn baby.

- If you are able to get pregnant, use an effective method of birth control while you are taking XPOVIO and for at least 1 week after your last dose. This is to ensure you do not become pregnant.
- If you become pregnant, or think you are pregnant, tell your healthcare professional right away.
- It is not known if XPOVIO passes into your breast milk. Do not breast-feed your baby during treatment with XPOVIO and for at least 1 week after your last dose.

Male patients: During your treatment with XPOVIO, use an effective method of birth control each time you have sex with a woman who can get pregnant. Continue this birth control for at least 1 week after your last dose.

Fertility for females and males: Taking XPOVIO may make it more difficult for you to have a child in the future.

XPOVIO can cause serious side effects, including:

- **Problems with your blood including:**
 - **Neutropenia** (low white blood cell count): Low white blood cell counts can sometimes be severe. This may increase your risk for serious **infections** that can cause death. Your healthcare professional will monitor you for signs and symptoms of infection. They may give you antibiotics to treat an infection or other medicines to improve your white blood cell count.
 - **Thrombocytopenia** (low platelet count): This can lead to easy bruising or bleeding. Bleeding may be severe and can sometimes cause death. You may need a platelet transfusion or other medicines to help increase your platelet count. Your healthcare professional will also monitor you for signs of bleeding.
 - **Hyponatremia** (decreased sodium levels): This is when sodium levels in your blood are low. It can be severe or life-threatening. Low sodium levels in your blood can happen if you have nausea, vomiting, diarrhea, you become dehydrated, or if you have loss of appetite with XPOVIO. You may not have any symptoms of a low sodium level.
 - Your healthcare professional will do **blood tests** before you start taking XPOVIO. These tests will be repeated regularly during your treatment. They will be done more often during the first 2 to 3 months of treatment. The results of these tests will tell your healthcare professional how XPOVIO is affecting your white blood cell and platelet counts and your sodium levels. Throughout your treatment your healthcare professional will watch you for signs and symptoms of infection and bleeding. They may also talk to you about your diet and prescribe you fluid through a vein in your arm (intravenous (IV) fluid) if you are dehydrated.
- **Nausea, vomiting and diarrhea:** These can sometimes be severe. Your healthcare professional will prescribe medicines to help prevent or treat your nausea and vomiting as well as your diarrhea. You may also receive treatments to help prevent dehydration including IV fluids. It is important for you to also drink fluids to prevent dehydration.
- **Anorexia** (loss of appetite) and **weight loss:** You may lose your appetite and experience weight loss while you are taking XPOVIO. Your healthcare professional will monitor your weight and ask you questions about how much you are eating. They may adjust your XPOVIO dose if you have these side effects. They may also give you medicines to increase your appetite. It is important for you to also eat enough calories to help prevent weight loss.

- **Neurologic problems** such as dizziness, fainting, confusional state and changes in mood and behaviour. These may be worse if you are taking certain other medications. You should avoid situations that may cause you to become dizzy or cause confusion.
- **Cataracts:** This is an eye problem where the lens of the eye becomes cloudy. XPOVIO may cause cataracts or cause your cataract to get worse. If you notice changes with your vision, your healthcare professional may request an eye examination by an eye specialist (an ophthalmologist). You may need eye surgery to remove the cataract and fix your vision. If you need surgery for your cataracts, do not take XPOVIO for 24 hours before the surgery and for 72 hours (3 days) after.

See the “Serious side effects and what to do about them” table below, for more information on these and other serious side effects.

Driving and using machines: Before you do tasks that may require special attention, wait until you know how you respond to XPOVIO. If you are tired, confused or are dizzy do not drive or use tools or machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XPOVIO:

- a medicine used to treat bacterial infections called rifampin
- Medicines used to prevent seizures or to treat epilepsy or medicines used to treat a painful condition of the face called trigeminal neuralgia including carbamazepine and phenytoin
- an herbal remedy used to treat depression called St. John’s Wort

How to take XPOVIO:

- Exactly as your healthcare provider tells you. Do not decrease, stop, or change your dose on your own.
- XPOVIO will be given with bortezomib and dexamethasone in treatment cycles. Each cycle is 5 weeks (35 days) long.
- Take your XPOVIO on day 1 of each week in the cycle. You will take your XPOVIO only once each week. Take it with or without food.
 - Your healthcare professional will tell you how much and how often you will have each of bortezomib and dexamethasone.
- Swallow your XPOVIO tablets whole with water. Do not break, chew, crush, or divide the tablets.
- On the days you take XPOVIO, take it at about the same time.
- Your healthcare professional may recommend that you take other medicines before and during treatment with XPOVIO to help prevent nausea and vomiting. Take these exactly as you are told. Tell your healthcare professional if these medicines do not control your nausea and vomiting.
- You may also need to increase the amount of fluid you drink and food you eat during your treatment.

Usual dose:

100 mg once per week. This weekly dose is made by taking five 20 mg XPOVIO tablets on Day 1 of each week of the cycle.

If you experience certain side effects while taking XPOVIO your healthcare professional may stop, interrupt or change your dose to one of the following:

- 80 mg once per week: Take four 20 mg tablets on Day 1 of each week of the cycle.
- 60 mg once per week: Take three 20 mg tablets on Day 1 of each week of the cycle.
- 40 mg once per week: Take two 20 mg tablets on Day 1 of each week of the cycle.

Check your dose before starting your treatment. Only take your dose once per week.

Overdose:

If you think you, or a person you are caring for, have taken too much XPOVIO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of XPOVIO, skip the dose. Take your next dose at the regularly scheduled day and time.

If you vomit after taking a dose of XPOVIO, do not repeat the dose. Take your next dose of XPOVIO on the next scheduled day and time.

What are possible side effects from using XPOVIO?

These are not all the possible side effects you may have when taking XPOVIO. If you experience any side effects not listed here, tell your healthcare professional.

- abdominal pain
- altered taste
- blurry vision
- bruising
- constipation
- cough
- dehydration
- difficulty falling asleep
- dizziness, headache
- dry mouth
- fatigue, lack of energy
- gas
- hair loss
- heartburn
- decreased blood pressure
- night sweats
- nosebleed
- shortness of breath
- swelling of the hands or legs

XPOVIO can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment and will interpret the results.

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			
Anemia (low red blood cells): being short of breath, feeling very tired, loss of energy, weakness, irregular heartbeats, pale complexion		✓	
Cataracts (clouding of the lens of the eye): blurry vision, seeing double, sensitivity to light or glare, symptoms can be new or worsening	✓		
Decreased appetite	✓		
Decreased weight	✓		
Diarrhea: severe, at least 3 loose or liquid bowel movements in a day	✓		
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision, fatigue	✓		
Infections including: Sepsis (infection of the blood): fast heart rate, fever, confusion and rapid breathing Urinary tract infection: frequent urination, painful urination, blood in the urine Shingles: painful skin rash with blisters Upper and lower respiratory infections: cough, fatigue, fever, chills, flu-like symptoms Pneumonia (a lung infection) and bronchitis (inflammation of the airway): cough, fever, chills, shortness of breath that may only occur when climbing stairs, difficult and painful breathing		✓	
Nausea: feeling the need to vomit		✓	
Neurologic problems: dizziness, fainting, confusion, decreased awareness of things around you (delirium), problems thinking,		✓	

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	
seeing or hearing things that are not really there (hallucinations), sleepiness, drowsiness, memory problems, balance problems			
Neutropenia (low white blood cells): fever, fatigue, aches and pains, flu-like symptoms		✓	
Peripheral neuropathy (damage to nerves outside of the brain and spinal cord): weakness, numbness, pain, tingling, usually in the hands and feet		✓	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, weakness		✓	
Vomiting		✓	
COMMON			
Acute kidney injury: very little or no urine		✓	
Hyponatremia (low sodium level in blood): tiredness, weakness, confusion, achy, stiff or uncoordinated muscles		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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/adverse-reaction-reporting.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 XPOVIO between 2 and 30 °C.

Keep out of reach and sight of children.

If you want more information about XPOVIO:

- 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.forustherapeutics.com, or by calling 1-866-542-7500.

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