

**PrNINLARO<sup>®</sup>**  
**Ixazomib capsules**

**PATIENT MEDICATION INFORMATION**

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PRMCDA/CA/NINL/0068



ONCOLOGY

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **NINLARO**®

#### **Ixazomib capsules**

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

#### **Serious Warnings and Precautions**

NINLARO should be prescribed and managed by a healthcare professional experienced in the use of anticancer drugs.

- NINLARO is used together with two other drugs called lenalidomide and dexamethasone. Ask your healthcare professional for further information on their proper use and side effects. You should also read the patient medication information leaflet for these other drugs as well as this one.
- Before starting a new cycle of treatment with NINLARO, your healthcare professional will do blood tests to check if you have enough white blood cells and platelets.
- Avoid direct contact with the capsule contents. Do not crush, chew, or open the NINLARO capsule.

#### **What is NINLARO used for?**

NINLARO is used together with lenalidomide and dexamethasone, to treat adults with a type of cancer of the bone marrow called multiple myeloma. This is a cancer of the plasma cells (a type of white blood cell that produces antibodies). NINLARO is used in patients who have received at least one prior multiple myeloma treatment.

#### **How does NINLARO work?**

NINLARO is a proteasome inhibitor. Proteasomes play an important role in cells by breaking down unwanted proteins. NINLARO blocks proteasomes from working and causes a build-up of proteins in cells. This can cause cell death, especially in multiple myeloma cells because they are more likely to contain a higher amount of abnormal proteins.

#### **What are the ingredients in NINLARO?**

Medicinal ingredients: ixazomib (as ixazomib citrate)

Non-medicinal ingredients: Black iron oxide (present in 3 mg capsules), gelatin, magnesium stearate, microcrystalline cellulose, potassium hydroxide, propylene glycol, red iron oxide

(present in 2.3 mg and 4 mg capsules), shellac, talc, titanium dioxide, yellow iron oxide (present in 4 mg capsules)

**NINLARO comes in the following dosage forms:**

Capsules: 2.3 mg, 3 mg and 4 mg

**Do not use NINLARO if:**

- you are allergic to ixazomib or any of the other ingredients contained in NINLARO or the components of the container.

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

- have a history of bleeding
- have persistent nausea, vomiting, constipation and/or diarrhea
- have or have had liver problems
- have or have had kidney problems
- have or have had a rare blood condition resulting from blood clots in small blood vessels

**Other warnings you should know about:**

**Female patients**

**Pregnancy and birth control**

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional. NINLARO can harm your unborn baby.
- You should not become pregnant while being treated with NINLARO.
- If you are a woman who is able to become pregnant, you must use two forms of effective birth control during treatment and for up to three months (90 days) after your last dose of NINLARO. If using oral hormonal contraceptives (for example, the pill), an additional barrier method of contraception (for example, diaphragm or condom) must be used. Talk to your healthcare professional about birth control methods that may be right for you.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant while taking NINLARO.

**Breastfeeding**

- Do NOT breastfeed while you are taking NINLARO. It is not known if NINLARO passes into breast milk.

**Male patients**

- If you are a man with a female partner who is able to become pregnant, you must use

two forms of effective birth control during treatment and for up to three months (90 days) after your last dose of NINLARO. Talk to your healthcare professional about birth control methods that may be right for you.

- Tell your healthcare professional right away if your partner becomes pregnant.

### **Infections**

NINLARO may increase your risk of developing a painful skin rash with blisters on a small area of skin on one side of your face or body (shingles). Your doctor may give you antiviral drugs to decrease your risk of developing shingles.

### **Liver Problems**

During treatment with NINLARO, your healthcare professional will do blood tests to make sure your liver is working properly.

### **Children and Adolescents**

NINLARO has not been studied in children less than 18 years of age.

**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 NINLARO:**

- an antibiotic used to treat bacterial infections (rifampin)
- medicines used to prevent seizures or to treat epilepsy, or medicines used to treat a painful condition of the face called trigeminal neuralgia (carbamazepine and phenytoin)
- an herbal medicine used for depression (St. John's wort)

### **How to take NINLARO:**

- Take NINLARO exactly as your healthcare professional tells you to take it. Do not change your dose or stop taking NINLARO without talking to your healthcare professional first.
- Take NINLARO at least 1 hour before or at least 2 hours after food. On the days that you take both NINLARO and dexamethasone, do not take NINLARO and dexamethasone at the same time. Take dexamethasone with food.
- Swallow NINLARO capsules whole with water. Do not crush, chew or open the capsule.
- Avoid direct contact with the capsule contents. If the capsule breaks, avoid spreading the capsule contents and wear gloves and protective clothing during clean-up. If you accidentally get powder from the NINLARO capsule on your skin, wash the area well with soap and water. If you accidentally get powder from the NINLARO capsule in your eyes, flush your eyes well with water.
- Most patients will receive treatment until their disease gets worse. NINLARO treatment may also be stopped if you experience side effects that cannot be managed

### **Usual dose:**

- NINLARO is taken in “cycles”. Each cycle lasts 4 weeks (28 days).
  - The usual dose of NINLARO is one 4 mg capsule taken by mouth 1 time each week, on the same day of the week for the first 3 weeks of each cycle. Once a week on Days 1, 8, and 15 of a 28-day treatment cycle.
  - Take each dose of NINLARO at about the same time of day.
- You will also receive treatment with lenalidomide and dexamethasone.
  - Take lenalidomide and dexamethasone exactly as your healthcare professional tells you to.
  - Take lenalidomide daily on Days 1-21 of a 28-day treatment cycle.
  - Take dexamethasone on Days 1, 8, 15, and 22 of a 28-day treatment cycle.

#### **Dosing Schedule: NINLARO taken with Lenalidomide and Dexamethasone**

✓ Take medicine

<b>28-Day Cycle (a 4-week cycle)</b>								
	<b>Week 1</b>		<b>Week 2</b>		<b>Week 3</b>		<b>Week 4</b>	
	Day 1	Days 2-7	Day 8	Days 9-14	Day 15	Days 16-21	Day 22	Days 23-28
NINLARO	✓		✓		✓			
Lenalidomide	✓	✓ Daily	✓	✓ Daily	✓	✓ Daily		
Dexamethasone	✓		✓		✓		✓	

#### **Overdose:**

Accidental overdose can cause serious side effects, including death.

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

Always follow dosage directions carefully. Your healthcare professional will talk to you about the correct dose to take.

#### **Missed Dose:**

If you miss a dose of NINLARO, or if you are late taking a dose, take the dose as long as the next scheduled dose is more than 3 days (72 hours) away. Do not take a missed dose if it is within 3 days (72 hours) of your next scheduled dose. Do not take a double dose to make up for a missed dose.

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

## What are possible side effects from using NINLARO?

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

- nausea
- vomiting
- constipation
- abdominal pain
- feeling tired or weak
- fever
- muscle or bone pain, including back, chest, arm, leg or joint pain
- muscle spasms or muscle cramps
- skin rash
- itchy skin
- cold or cold-like symptoms, inflammation of nasal passages
- bronchitis with cough, wheezing, or difficulty breathing
- decreased appetite
- low blood levels of potassium (shown in blood tests)
- trouble sleeping
- dizziness
- fall
- headache
- cough
- feeling short of breath
- loss of weight
- cataracts
- blurred vision, dry eyes, whites of your eyes look red or pink
- involuntary shaking

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			
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness	✓		
Neutropenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms	✓		

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	
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness	✓		
Diarrhea	✓		
<b>Peripheral Neuropathy</b> (damage to the nerves located outside of the brain and spinal cord): Numbness, tingling, burning sensation, or pain in hands or feet, weakness in arms or legs	✓		
<b>Peripheral edema</b> (swelling of the legs or hands caused by fluid retention): Swelling of arms, hands, legs, ankles, or feet, sudden weight gain	✓		
<b>Pneumonia</b> (infection in the lungs): Cough, fever, chills	✓		
<b>COMMON</b>			
<b>Herpes Zoster virus</b> (shingles): Painful blisters on a small area of skin on one side of face or body		✓	
<b>Liver problems:</b> Yellowing of skin and eyes, stomach pain or swelling, nausea or vomiting		✓	

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	
RARE			
<b>Cutaneous Vasculitis</b> (inflammation of blood vessels in the skin): Red to purple bumps on skin or rash with skin peeling and mouth sores		✓	
<b>Transverse myelitis</b> (inflammation of the spinal cord): Muscle weakness, loss of feelings of the toes and feet or loss of leg movement		✓	
<b>Posterior reversible encephalopathy syndrome (PRES)</b> (a rare neurological disorder): Changes in vision, changes in mental status, or seizures		✓	
<b>Tumour Lysis Syndrome</b> (the sudden, rapid death of cancer cells due to the treatment): Dizziness, decreased urination, confusion, vomiting, nausea, swelling, shortness of breath, or heart rhythm disturbances		✓	
<b>Thrombotic microangiopathy (TMA), including thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)</b> (rare blood conditions resulting from blood clots in small blood vessels): Weakness, nausea, vomiting, diarrhea, fatigue, fever, bruising, bleeding (e.g., nose bleeds), decreased urination, swelling, confusion, vision loss, or seizures			✓
<b>Severe skin reactions, including Stevens-Johnson syndrome</b>			✓

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	
<b>[SJS], toxic epidermal necrolysis [TEN], and drug reaction with eosinophilia and systemic symptoms [DRESS]:</b> skin rash that spreads quickly, redness, fever, enlarged lymph nodes, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genital			
<b>Anaphylactic reaction:</b> swelling of the face, lips, tongue or throat, trouble breathing or swallowing, wheezing, chest tightness or dizziness, skin itching and hives			✓

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.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 NINLARO at 15-30°C. Do not freeze.

Store capsules in original packaging until immediately prior to use.

Keep out of reach and sight of children.

### If you want more information about NINLARO:

- 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.takeda.com/en-ca](http://www.takeda.com/en-ca), or by calling 1-800-268-2772.

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