



 Pr **NINLARO**[®]
(ixazomib) capsules

IMPORTANT INFORMATION
FOR STARTING TREATMENT
WITH NINLARO[®]



ONCOLOGY

GETTING READY TO START NINLARO

YOUR NEW TREATMENT FOR MULTIPLE MYELOMA

Now that you have been prescribed NINLARO (ixazomib), it's important that you have information about your new treatment. Read this brochure before you start taking NINLARO. It offers a brief description of NINLARO: how it works, how to take it, and what to expect. This information does not take the place of talking with your healthcare professional about your medical condition or your treatment.

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.

About multiple myeloma and NINLARO

What is multiple myeloma?

Multiple myeloma is a cancer of the plasma cells. Plasma cells are a type of white blood cell that produces antibodies. These cells originate in the bone marrow.

Multiple myeloma develops when abnormal plasma cells begin to divide uncontrollably and accumulate in the bone marrow. These abnormal plasma cells make abnormal proteins that build up in the bone marrow.



What is NINLARO?

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.

Taking NINLARO



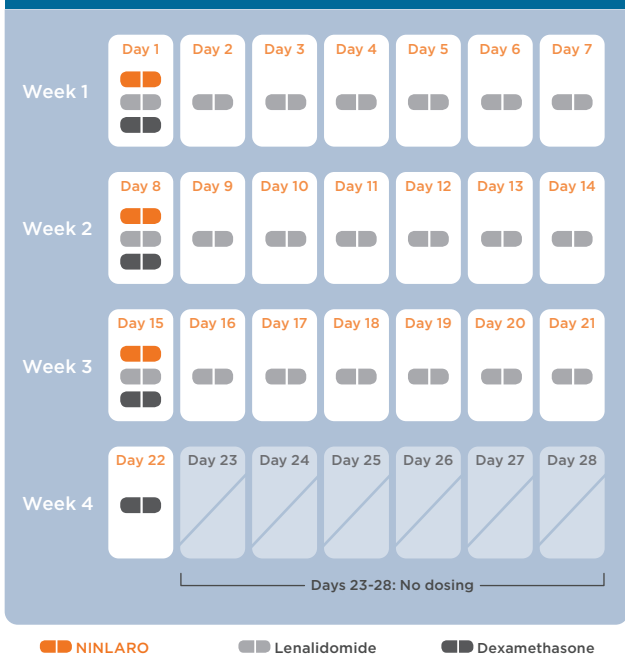
How should I take NINLARO?

- 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.

Dosing schedule: NINLARO taken with lenalidomide and dexamethasone



- 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



What should I do if I miss a dose of NINLARO?

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 should I do if I take too much NINLARO?

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.

Additional information



How should I store NINLARO?

Store NINLARO at 15-30°C. Do not freeze. Store capsules in original packaging until immediately prior to use.

Keep NINLARO out of reach and sight of children.



What else should I know about NINLARO?

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

Important safety information

- NINLARO is used together with two other drugs called lenalidomide and dexamethasone. Read the patient medication information leaflet for lenalidomide and ask your healthcare professional for further information on their proper use and side effects
- 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

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

Additional important safety information



What should I tell my healthcare professional before taking NINLARO?

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 safety information 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)



What are possible side effects of NINLARO?

These are not all the possible side effects you may have when taking NINLARO. If you experience any side effects, including any not listed here, contact 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

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

Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness

Diarrhea

Peripheral Neuropathy (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

Peripheral edema (swelling of the legs or hands caused by fluid retention): Swelling of arms, hands, legs, ankles, or feet, sudden weight gain

Pneumonia (infection in the lungs): Cough, fever, chills

COMMON

Herpes Zoster virus (shingles): Painful blisters on a small area of skin on one side of face or body

Liver problems: Yellowing of skin and eyes, stomach pain or swelling, nausea or vomiting

RARE

Cutaneous Vasculitis (inflammation of blood vessels in the skin): Red to purple bumps on skin or rash with skin peeling and mouth sores

Transverse myelitis (inflammation of the spinal cord): Muscle weakness, loss of feelings of the toes and feet or loss of leg movement

Posterior reversible encephalopathy syndrome (PRES) (a rare neurological disorder): Changes in vision, changes in mental status, or seizures

Tumour Lysis Syndrome (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

Thrombotic microangiopathy (TMA), including thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS) (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

Severe skin reactions, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS): 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

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.

Talk to your healthcare professional		Stop taking drug and get immediate medical help
Only if severe	In all cases	
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Remembering your medicine

In this section we discuss tips for taking your medicine as prescribed (commonly known as adherence). This includes taking medications in the right amount and at the right time of day.



Tips for remembering

Forgetting medication is a common reason for nonadherence.

Consider the following tools and techniques to help you remember to take your medication:

- Build a routine and take your medication during a certain activity (e.g., brushing your teeth, getting ready)
- Keep track of the doses you've taken by recording each one in a medication diary
- Set alarms (e.g., watches, smartphones, text/call reminders)





Communicating with your care team

- Create and maintain a good relationship with your care team
- Ask questions to fully understand your treatment and potential side effects, and clarify anything that's confusing

Talk with your care team about tips to help you remember to take your medication. 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.





Important contacts

My oncologist

Name: _____

Address: _____

Phone: _____

E-mail: _____

My primary care doctor

Name: _____

Address: _____

Phone: _____

E-mail: _____

My pharmacist/pharmacy

Name: _____

Address: _____

Phone: _____

E-mail: _____

My nurse

Name: _____

Address: _____

Phone: _____

E-mail: _____

My health insurance company

Name: _____

Phone: _____

E-mail: _____

Emergency contacts

(In case of emergency, dial 911)

Name: _____

Address: _____

Phone: _____

E-mail: _____

Name: _____

Address: _____

Phone: _____

E-mail: _____



Support resources

The following organizations and advocacy groups can provide additional education and support:

Myeloma Canada
www.myeloma.ca

Canadian Cancer Society
www.cancer.ca

Multiple Myeloma Research Foundation
www.themmrp.org

International Myeloma Foundation
www.myeloma.org



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