

Packaging Instructions



Open the NINLARO package with confidence

NINLARO comes in a type of package you may not have experience with. This guide contains step-by-step instructions for handling your NINLARO package and capsules. These packaging instructions can also be found within the NINLARO Starter Kit and NINLARO Experience Brochure.



- 1** Before you can open the package, be sure to **push the medication card all the way into the sleeve** to help with the release. NINLARO is also available in 3 mg and 2.3 mg dosing strengths. Note: all dosing strengths are in similar packaging.
- 2** **Press in with your thumb** to release the locking mechanism.
- 3** While pressing in with your thumb, **pull out the medication card** using the thumb and index finger of your other hand.
- 4** Gently **push the capsule** through the foil by pressing on the top or bottom of the capsule. Avoid putting direct pressure on the center of the capsule.
- 5** Avoid direct contact with capsule contents. Swallow the capsule whole. Do not crush, chew, or open the capsule. After you take your medication, wash your hands with soap and water.



Always store NINLARO in its original packaging until it is time to take it.

Please read the Important Safety Information on page 2-3 and the Patient Information in the accompanying full Prescribing Information.



Indication and Important Safety Information

Indication and Important Safety Information for NINLARO® (ixazomib)

What is NINLARO?

NINLARO is a prescription medicine used to treat multiple myeloma in combination with the medicines REVLIMID® (lenalidomide) and dexamethasone, in people who have received at least one prior treatment for their multiple myeloma.

NINLARO should **not** be used to treat the following people, unless they are participants in a controlled clinical trial:

- people who are receiving maintenance treatment, **or**
- people who have been newly diagnosed with multiple myeloma.

It is not known if NINLARO is safe and effective in children.

Important Safety Information for NINLARO® (ixazomib)

NINLARO may cause serious side effects, including:

- **Low platelet counts (thrombocytopenia)** are common with NINLARO and can sometimes be serious. You may need platelet transfusions if your counts are too low. Tell your healthcare provider if you have any signs of low platelet counts, including bleeding and easy bruising.
- **Stomach and intestinal (gastrointestinal) problems.** Diarrhea, constipation, nausea, and vomiting are common with NINLARO and can sometimes be severe. Call your healthcare provider if you get any of these symptoms and they do not go away during treatment with NINLARO. Your healthcare provider may prescribe medicine to help treat your symptoms.
- **Nerve problems** are common with NINLARO and may also be severe. Tell your healthcare provider if you get any new or worsening symptoms including: tingling, numbness, pain, a burning feeling in your feet or hands, or weakness in your arms or legs.
- **Swelling** is common with NINLARO and can sometimes be severe. Tell your healthcare provider if you develop swelling in your face, arms, hands, legs, ankles, or feet, or if you gain weight from swelling.
- **Skin reactions.** Rashes are common with NINLARO. NINLARO can cause rashes and other skin reactions that can be serious and can lead to death. Tell your healthcare provider right away if you get a new or worsening rash, severe blistering or peeling of the skin, or mouth sores.
- **Thrombotic microangiopathy (TMA).** This is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs, and may lead to death. Get medical help right away if you get any of the following signs or symptoms during treatment with NINLARO: fever, bruising, nose bleeds, tiredness, or decreased urination.
- **Liver problems.** Tell your healthcare provider if you get these signs of a liver problem: yellowing of your skin or the whites of your eyes; pain in your right upper stomach-area (abdomen).

Other common side effects of NINLARO include low white blood cell counts (neutropenia) and bronchitis. Tell your healthcare provider if you get new or worsening signs or symptoms of the following during treatment with NINLARO:

- skin rash and pain (shingles) due to reactivation of the chicken pox virus (herpes zoster)
- blurred vision or other changes in your vision, dry eye, and pink eye (conjunctivitis)

Indication and Important Safety Information (Continued)

These are not all the possible side effects of NINLARO. Talk to your healthcare provider for medical advice about side effects. **You may report side effects to Takeda at 1-844-217-6468 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before taking NINLARO, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems.
- have kidney problems or are on dialysis.
- are pregnant or plan to become pregnant. NINLARO can harm your unborn baby.

Females who are able to become pregnant:

- o Avoid becoming pregnant during treatment with NINLARO.
- o Your healthcare provider will do a pregnancy test before you start treatment with NINLARO.
- o You should use effective non-hormonal birth control during treatment and for 90 days after your last dose of NINLARO. If using hormonal contraceptives (for example, birth control pills), you should also use an additional barrier method of contraception (for example, diaphragm or condom). Talk to your healthcare provider about birth control methods that may be right for you during this time.
- o Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with NINLARO.

Males with female partners who are able to become pregnant:



- o You should use effective birth control during treatment and for 90 days after your last dose of NINLARO.
- o Tell your healthcare provider right away if your partner becomes pregnant or thinks she may be pregnant while you are being treated with NINLARO.
- are breastfeeding or plan to breastfeed. It is not known if NINLARO passes into breast milk, if it affects an infant who is breastfed, or breast milk production. Do not breastfeed during treatment with NINLARO and for 90 days after your last dose of NINLARO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Talk to your healthcare provider before starting any new medicines during treatment with NINLARO.

Taking too much NINLARO (overdose) can cause serious side effects, including death. If you take more NINLARO than instructed by your healthcare provider, call your healthcare provider right away or go to the nearest hospital emergency room right away. Take your medicine pack with you.

Please see Patient Information in the accompanying NINLARO (ixazomib) full Prescribing Information.



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