MULTIPLE MYELOMA RELAPSE GUIDE

Partnering with your care team to understand the importance of **monitoring your M protein**



Please read the Important Safety Information on page 6-7 and the <u>Patient Information</u> in the accompanying full <u>Prescribing Information</u>.

Visit <u>www.ninlaro.com</u> to learn more

Relapses in multiple myeloma are expected

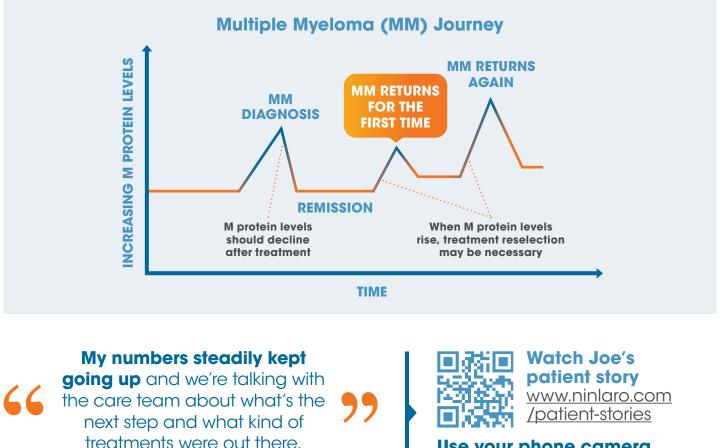
-Joe, real patient.

(ixazomib)capsules

4mg 3mg 2.3mg

One out of three people with multiple myeloma will have **no or minimal symptoms** the first time they relapse

Not everyone will have symptoms when multiple myeloma returns (also known as a relapse), so it's important to continue to monitor your multiple myeloma with lab tests. When multiple myeloma comes back, lab tests will show **increasing levels of an abnormal antibody called M protein**. If your multiple myeloma relapses without symptoms, it can feel unexpected, but this is not unusual.



Use your phone camera to scan the QR code

Your M protein levels matter for your multiple myeloma journey

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Increasing M protein levels are a sign of multiple myeloma relapse

Multiple myeloma cells make an abnormal antibody called M protein. M protein can accumulate in the blood or urine of people with multiple myeloma and **increasing levels can be an early sign of a relapse**.

Your journey with multiple myeloma is unique and so are your M protein levels. It's important to note that some people have myeloma cells that produce very little M protein, whereas others produce a lot of M protein.



How do you know if M protein levels are increasing?

Your healthcare team will monitor your multiple myeloma on a regular basis using several different lab tests and imaging. **Increasing M protein Ievels can be identified by an M spike**. An M spike is seen on tests when elevated levels of M protein are detected in your blood or urine.

It's important to have a proactive conversation with your healthcare team so you know what your current M protein levels are and can be ready with a plan if your start to see them increase.

How can I track my M protein levels and lab tests?



Use the lab test tracker to record your test results after each visit

Download the lab test tracker www.ninlaro.com/lab-test-tracker



Early treatment can make a difference

It may be beneficial for your healthcare provider to change your multiple myeloma treatment as soon as there are signs you are starting to relapse, even if you are not experiencing symptoms yet. In a study of patients experiencing a first multiple myeloma relapse, **early treatment resulted in better outcomes** for patients whose M protein levels were increasing and who weren't experiencing any symptoms.



Keep your **"on-the-go" lifestyle** with NINLARO[®] (ixazomib)

With no travel to the clinic required for administration, you can take the all-oral NINLARO treatment combination* at home, on the go, or wherever life takes you



Individual results may vary. *The NINLARO treatment combination=NINLARO + lenalidomide + dexamethasone.

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.



NINLARO is the **first and only oral medication** of its kind, a proteasome inhibitor, that may help when multiple myeloma relapses

The US Food and Drug Administration (FDA) approved NINLARO based on the results of a clinical study. This study tested the NINLARO treatment combination (NINLARO + lenalidomide + dexamethasone) compared with placebo + lenalidomide + dexamethasone in 722 people whose multiple myeloma had come back or stopped responding to prior therapy. It measured the length of time a patient lived without their disease getting worse.



Most people had a response.

78% of people responded to the NINLARO treatment combination (vs 72% with the lenalidomide + dexamethasone combination).



Fast responses.

The NINLARO treatment combination was proven to work fast. Of the people who responded to it, half of them saw their first response in less than 1.1 months (the other half taking the NINLARO treatment combination took longer to see a response) compared with about 2 months for the lenalidomide + dexamethasone combination.



Deepened responses over time.

Response to the NINLARO treatment combination deepened with more time on treatment. For example, twice as many people saw a complete response^t to treatment (disappearance of the M protein) after 12 months compared to after 6 months. Responses improved over time for both treatment combinations in the study.



Most common adverse reactions.

The most common adverse reactions with NINLARO (≥20%) are low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), diarrhea, constipation, nerve problems (peripheral neuropathy), nausea, swelling, rash, vomiting, and bronchitis.

^tComplete response is when there are less than 5% plasma cells in the bone marrow and blood and urine lab tests show no M protein.



Indication and Important Safety Information

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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)

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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:

- Avoid becoming pregnant during treatment with NINLARO.
- Your healthcare provider will do a pregnancy test before you start treatment with NINLARO.
- 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.
- 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:

- You should use effective birth control during treatment and for 90 days after your last dose of NINLARO.
- 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.



Partner with your care team to prepare for a first multiple myeloma relapse

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Think about your treatment priorities before you talk with your care team

You can start thinking about what you want from your next treatment, even before your multiple myeloma relapses. There's a good reason not to wait — early treatment has been shown to benefit people whose multiple myeloma relapses even if they aren't experiencing symptoms yet.

Start preparing by considering:

- What your goals and hopes for your next treatment are.
- How busy your daily lifestyle is.
- What kind of travel plans you may want to make.
- How easy is it for you to get to and from appointments with your care teams.
- Any side effects that you may be concerned about.

Questions you may want to ask your care team about first relapse

- How can I know if my M protein levels are increasing?
- What can I do to plan for when my multiple myeloma relapses?
- If my M protein levels are increasing, at what point should we consider a treatment change?
- What are my next treatment options?
- · How will a treatment change impact my lifestyle?
- Can I keep taking my current medications when my multiple myeloma treatment changes?
- How will I know that a treatment change is working?

When discussing post-relapse treatment options with patients,
I ensure we discuss any lifestyle and logistical considerations
that may make frequent office visits more taxing.

- Dr. Saulius Girnius



Takeda Pharmaceuticals U.S.A., Inc. 40 Landsdowne Street, Cambridge, MA 02139 Visit www.ninlaro.com to learn more

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