NINLARO® (ixazomib) capsules
4mg | 3mg | 2.3mg

ACCESS GUIDE

Image for illustration purposes; exact packaging may vary.

INDICATION AND USAGE

Indication: NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO. Platelet nadirs typically occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle. Grade 3 thrombocytopenia was reported in 17% of patients in the NINLARO regimen and Grade 4 thrombocytopenia was reported in 13% in the NINLARO regimen. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

Takeda Oncology Here2Assist®

Please see **page 3** to learn more.

Takeda | ONCOLOGY

Distribution network as of August 2024

Specialty Pharmacy and Distribution Network for NINLARO® (ixazomib)

DISTRIBUTION DETAILS

Product name	NINLARO® (ixazomib) capsules, for oral use
Distributed and marketed by	Takeda Pharmaceuticals America, Inc.
Storage and handling	Store NINLARO at room temperature. Do not store above 86°F (30°C). Do not freeze. Store capsules in original packaging until immediately prior to use.
Dosing of NINLARO	The recommended starting dose of NINLARO is 4 mg administered orally once a week on Days 1, 8, and 15 of a 28-day treatment cycle.

How supplied

Strength	Package Configuration	NDC	Capsules
4 mg	**Outer carton** Three 4 mg capsules in a carton **3 count blister pack** Each blister pack has three 4 mg capsules **1 count blister pack** Each blister pack has one 4 mg capsule	**Outer carton** 63020-400-02	Light orange, size 3, imprinted with "Takeda" on the cap and "4 mg" on the body in black ink
3 mg	**Outer carton** Three 3 mg capsules in a carton **3 count blister pack** Each blister pack has three 3 mg capsules **1 count blister pack** Each blister pack has one 3 mg capsule	**Outer carton** 63020-390-02	Light grey, size 4, imprinted with "Takeda" on the cap and "3 mg" on the body in black ink
2.3 mg	**Outer carton** Three 2.3 mg capsules in a carton **3 count blister pack** Each blister pack has three 2.3 mg capsules **1 count blister pack** Each blister pack has one 2.3 mg capsule	**Outer carton** 63020-230-02	Light pink, size 4, imprinted with "Takeda" on the cap and "2.3 mg" on the body in black ink

Ordering

Specialty Pharmacies

NINLARO can be ordered from one of the following specialty pharmacies*:

Biologics
1-800-850-4306
biologics.mckesson.com

Onco360 Specialty Pharmacy
1-877-662-6633
onco360.com

Walgreens Specialty Pharmacy
1-888-782-8443
WalgreensSpecialtyRx.com

CVS Specialty
1-855-539-4712
cvsspecialty.com

Accredo
1-877-732-3431
accredo.com

Optum
1-855-427-4682
optum.com

Specialty Distributors

NINLARO may be purchased directly from qualified entities† from the following distribution partners:

ASD Healthcare
1-800-746-6273
asdhealthcare.com

Cardinal Health
1-855-855-0708
cardinalhealth.com

McKesson Specialty Care
1-800-482-6700
mckesson.com

McKesson Plasma and Biologics
1-877-625-2566
mckesson.com

Oncology Supply
1-800-633-7555
oncologysupply.com

NDC, National Drug Code.

*NINLARO prescriptions should be filled through one of these in-network specialty pharmacies. Sending a NINLARO prescription to an alternate pharmacy may result in delay or nonfulfillment of the prescription.

†Qualified entities for direct purchase include hospitals, physician practices, and institutions that have been licensed by a state agency to dispense pharmaceutical products to appropriate patients. Direct purchase is not available to specialty pharmacy providers or retail pharmacies who are not themselves part of a qualified entity. Eligible government entities include the Department of Defense, Department of Veterans Affairs, and 340B covered entities.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

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4mg | 3mg | 2.3mg

Takeda Oncology Here2Assist®

We're here to help your patients with their coverage, financial, and educational resource needs

Committed to supporting your patients

Takeda Oncology Here2Assist® is a comprehensive support program committed to helping your patients navigate coverage requirements, identify available financial assistance, and connect with helpful resources throughout their Takeda Oncology treatment.

- Works with your patient's insurance company to help get your patient started on their medication
- Identifies available financial assistance that may be right for your patients
- Identifies specialty pharmacies to help fill and ship your patients' prescriptions appropriately
- Conducts regular follow-up calls to patients

Visit us at https://www.here2assist.com/hcp to learn more

Daryl
Takeda Oncology Here2Assist® patient

Important Safety Information (Cont'd)

WARNINGS AND PRECAUTIONS (CONT'D)

- **Gastrointestinal Toxicities,** including diarrhea, constipation, nausea and vomiting were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 3% of patients in the NINLARO regimen and 2% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.
- **Peripheral Neuropathy** was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (24% and 17% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (<1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 4% of patients in the NINLARO regimen and <1% of patients in the placebo regimen. During treatment, monitor patients for symptoms of neuropathy and consider adjusting dosing for new or worsening peripheral neuropathy.
- **Peripheral Edema** was reported with NINLARO. Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of NINLARO for Grade 3 or 4 symptoms or dexamethasone per its prescribing information.
- **Cutaneous Reactions.** Stevens-Johnson syndrome and toxic epidermal necrolysis, including fatal cases, have been reported with NINLARO. If Stevens-Johnson syndrome or toxic epidermal necrolysis occurs, discontinue NINLARO and manage as clinically indicated. Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in <1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.
- **Thrombotic Microangiopathy** has been reported with NINLARO. Fatal cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), have been reported in patients who received NINLARO. Monitor for signs and symptoms of TTP/HUS. If the diagnosis is suspected, stop NINLARO and evaluate. If the diagnosis of TTP/HUS is excluded, consider restarting NINLARO. The safety of reinitiating NINLARO therapy in patients previously experiencing TTP/HUS is not known.
- **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in <1% of patients treated with NINLARO. Hepatotoxicity has been reported (10% in the NINLARO regimen and 9% in the placebo regimen). Monitor hepatic enzymes regularly and adjust dosing for Grade 3 or 4 symptoms.
- **Embryo-fetal Toxicity:** NINLARO can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with NINLARO and for 90 days following the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with NINLARO and for 90 days following the last dose.
- **Increased Mortality in Patients Treated with NINLARO in the Maintenance Setting:** In two prospective randomized clinical trials in multiple myeloma in the maintenance setting, treatment with NINLARO resulted in increased deaths. Treatment of patients with NINLARO for multiple myeloma in the maintenance setting is not recommended outside of controlled trials.

ADVERSE REACTIONS

The most common adverse reactions (≥ 20%) in the NINLARO regimen compared to placebo in combination with lenalidomide plus dexamethasone, respectively were thrombocytopenia (85%, 67%; pooled from adverse event and laboratory data), neutropenia (74%, 70%; pooled from adverse event and laboratory data), diarrhea (52%, 43%), constipation (35%, 28%), peripheral neuropathy (32%, 24%), nausea (32%, 23%), edema peripheral (27%, 21%), rash (27%, 16%), vomiting (26%, 13%), and bronchitis (22%, 17%). Serious adverse reactions reported in ≥ 2% of patients in the NINLARO regimen included diarrhea (3%), thrombocytopenia (2%), and bronchitis (2%).

DRUG INTERACTIONS: Avoid concomitant administration of NINLARO with strong CYP3A inducers.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Advise women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.
- **Hepatic Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.
- **Renal Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with severe renal impairment or end-stage renal disease requiring dialysis. NINLARO is not dialyzable.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals at 1-844-617-6468 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see accompanying NINLARO® (ixazomib) full Prescribing Information.

To learn more about NINLARO, please visit NINLAROhcp.com.

Reference: Ninlaro. Prescribing Information. Takeda Pharmaceuticals America, Inc.; July 2024.

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