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

ACCESS GUIDE

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 update effective starting November 01 2022

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	Count	NDC*	Capsules
4 mg	Carton of three single blister packs, with each blister containing one 4 mg capsule	**Outer carton** 63020-400-02 **Blister pack** 63020-400-01	Light orange, size 3, imprinted with "Takeda" on the cap and "4 mg" on the body in black ink
3 mg	Carton of three single blister packs, with each blister containing one 3 mg capsule	**Outer carton** 63020-390-02 **Blister pack** 63020-390-01	Light grey, size 4, imprinted with "Takeda" on the cap and "3 mg" on the body in black ink
2.3 mg	Carton of three single blister packs, with each blister containing one 2.3 mg capsule	**Outer carton** 63020-230-02 **Blister pack** 63020-230-01	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
1-877-662-6633
onco360.com

AllianceRx
1-888-782-8443
alliancerxwp.com

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

Accredo
1-877-732-3431
accredo.com

Optum
1-855-427-4682
optum.com

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.

Specialty Distributors

NINLARO may be purchased directly 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.

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

Takeda Oncology Here2Assist®

- Works with your patients' insurance company to help get your patient started on their medication
- Identifies available financial assistance that may be right for your patients
- May help eligible patients get started on treatment in the event of an insurance delay
- Identifies specialty pharmacies to help fill and ship your patients' prescriptions appropriately
- Conducts regular follow-up calls to patients
- Sends text message status updates and reminders to patients*

For more information about patient access support and financial assistance that your patients may qualify for, call us at 1-844-817-6468, Option 2. Let's Talk. We're available Monday-Friday, 8AM–8PM ET, or visit us at www.Here2Assist.com/hcp to learn more.

The Takeda Oncology Here2Assist RapidStart Program

If your patient experiences a delay in insurance coverage determination of at least 5 business days, your patient may be eligible to receive a 1-month supply of medication at no cost to them. Terms and Conditions apply†

Visit www.Here2Assist.com to download the appropriate RapidStart Request Form.

Takeda Oncology Co-Pay Assistance Program

For patients who are commercially insured and concerned about their out-of-pocket costs, the Takeda Oncology Co-Pay Assistance Program‡ may be able to help

- Your patient could pay as little as $0 per prescription. Terms and Conditions apply‡

Visit www.TakedaOncologyCopay.com or call to speak with a Takeda Oncology Here2Assist case manager at 1-844-817-6468, Option 2, Monday-Friday, 8AM–8PM ET.

Takeda Oncology Patient Assistance Program

If your patient is uninsured or the prescribed medication is not covered, the patient may be eligible to receive their Takeda Oncology medication at no cost through our Patient Assistance Program§

Visit www.Here2Assist.com to download the Patient Assistance Program Application.

*Patients will need to enroll in the texting program to receive text messages.

†The RapidStart Program provides a 1-month supply of treatment of the prescribed Takeda Oncology medication at no charge for eligible patients new to therapy experiencing a delay in insurance coverage determination of at least 5 business days. There is no purchase obligation by virtue of a patient's participation in the RapidStart Program. Patients must have an on-label, valid prescription for the Takeda Oncology medication, and a medical necessity for being prescribed the Takeda Oncology medication. Patients must be enrolled in the Takeda Oncology Here2Assist Program to qualify. Free product for the RapidStart Program will only be available through the RapidStart Program noncommercial specialty pharmacy. A delay in coverage determination of at least 5 days is required for patients to be eligible for the RapidStart Program. The program may not be combined with any other offer and is not available to patients whose insurers have made a final determination to deny the patient coverage for the prescribed Takeda Oncology medication. Takeda reserves the right to change or end the program at any time. Benefits provided under the program are not transferable.

‡By enrolling in the Takeda Oncology Co-Pay Assistance Program (the "Program"), you acknowledge that you currently meet the eligibility criteria and will comply with the following terms and conditions: You must be at least 18 years old, a resident of the United States or a US Territory, and have commercial (private) prescription insurance that does not cover the entire cost of the medication. The Program is not valid for patients whose prescription claims are eligible to be reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicare, Medicare Advantage, Medigap, Medicaid, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. Patients who become eligible for or start using government insurance will no longer be eligible for the Program. The Program is not valid if the entire cost of your prescription is reimbursable by a private insurance plan or other private health or pharmacy benefit programs. You are responsible for reporting receipt of Program assistance to any insurer, health plan, or other third party who pays for or reimburses any part of the medication cost, as may be required. You agree that you will not submit the cost of any portion of the product dispensed pursuant to this Program to a federal or state healthcare program (including, but not limited to, Medicare, Medicare Advantage, Medicaid, TRICARE, VA, DOD, etc.), for purposes of counting it toward your out-of-pocket expenses, and to notify Takeda Oncology Here2Assist® if you become eligible for a federal or state healthcare program. This Program is not conditioned on any past, present or future purchase of any Takeda product, including refills. This Program is valid for 12 months, and your co-pay card may be renewed every 12 months, subject to continued eligibility. This offer is not valid with any other program, discount, or offer involving your prescribed Takeda Oncology medication. This offer may be rescinded, revoked, or amended without notice. No reproductions. This offer is void where prohibited by law, taxed, or restricted. Limit one offer per purchase. No income requirements or membership fees. This Program is not health insurance. Cash value of 1/100 of 1¢. For questions about this offer, please contact the Takeda Oncology Co-Pay Assistance Program, a patient support service of Takeda Oncology Here2Assist, at 1-844-817-6468, Option 2, Monday-Friday, 8AM-8PM ET.

§To be eligible for the Patient Assistance Program, patients must meet certain financial and insurance coverage criteria. A Patient Assistance Program Application must be submitted in order to confirm patient eligibility.

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,** including a fatal case of Stevens-Johnson syndrome, were reported with NINLARO. If Stevens-Johnson syndrome 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.

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.; May 2022.

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