



**NINLARO**<sup>®</sup>  
(ixazomib) capsules  
4mg | 3mg | 2.3mg

## **DOSING GUIDE**

### **Indication**

NINLARO<sup>®</sup> (ixazomib) is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Please see **Important Safety Information** on pages 20-21 and accompanying NINLARO (ixazomib) full Prescribing Information.



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Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib) full [Prescribing Information](#).

## The NINLARO® (ixazomib) regimen\* offers the convenience of oral administration<sup>1-3</sup>

### Dosing

- The recommended starting dose of NINLARO is 4 mg (one capsule) in combination with lenalidomide and dexamethasone<sup>1†</sup>

### ► Communicating with your patients

*Tips and reminders have been included in this brochure to facilitate communication with patients. You can recognize them by their orange callout box.*



Share the following information at the start of treatment to ensure patients and caregivers are well informed:

- Drug and indication
- Dose and dosing schedule
- Start date
- Handling instructions
- Administration and what to do if a dose is missed or too much NINLARO is taken
- Food and drug interactions
- Side effects and management




\*The NINLARO regimen includes NINLARO+lenalidomide+dexamethasone.  
†A 3-mg starting dose is recommended for patients with moderate or severe hepatic impairment and patients with severe renal impairment or end-stage renal disease requiring dialysis. A 2.3-mg dose is also available for subsequent dose reductions due to adverse reactions (ARs).

## Plan for individualized adherence strategies<sup>4</sup>

- Have patients build a routine and take medication during a certain activity every day
- Encourage patients to keep track of each dose by keeping a medication diary
- Help set alarms (eg, watches, smartphones, text/call reminders)

## ▶ Treatment should be continued until disease progression or unacceptable toxicity<sup>1</sup>

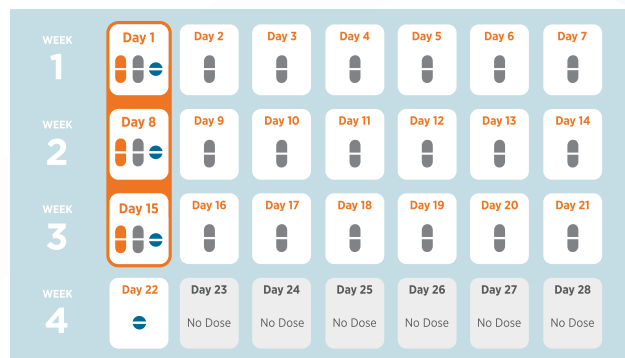
### NINLARO® (ixazomib) is available in the following capsule strengths<sup>1</sup>:

- **4 mg:** Light orange gelatin capsule imprinted with the  logo on the cap and 4 mg on the body in black ink
- **3 mg:** Light gray gelatin capsule imprinted with the  logo on the cap and 3 mg on the body in black ink
- **2.3 mg:** Light pink gelatin capsule imprinted with the  logo on the cap and 2.3 mg on the body in black ink

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib) full Prescribing Information.

## Dosing schedule<sup>1</sup>

- The recommended dosing schedule for each 28-day treatment cycle of:
  - NINLARO is 4 mg (one capsule) administered orally once a week on days 1, 8, and 15
  - Lenalidomide is 25 mg administered orally daily on days 1 through 21
  - Dexamethasone is 40 mg administered orally on days 1, 8, 15, and 22



 **NINLARO**  
(4 mg, 3 mg, 2.3 mg)     **Lenalidomide**  
(25 mg)     **Dexamethasone**  
(40 mg)

- Advise patients to take NINLARO once a week on the same day and at approximately the same time for the first 3 weeks of a 4-week cycle. The importance of carefully following all dosage instructions should be discussed with patients starting treatment. Advise patients to take the recommended dosage as directed because overdosage has led to deaths

For more information on dosing administration requirements, see the next page.

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## NINLARO® (ixazomib) dosing considerations<sup>1</sup>

**NINLARO should not be taken with food. Food may interfere with the absorption of NINLARO, which may lower levels of the medication in the blood and possibly reduce effectiveness.**

- NINLARO should be taken on an empty stomach or at least 1 hour before or at least 2 hours after food
- NINLARO should not be taken at the same time as dexamethasone because **dexamethasone should be taken with food**
- **No body surface area dosing is required**
- **NINLARO should be swallowed whole with water and should not be crushed, chewed, or opened**
- **If a NINLARO dose is delayed or missed, the dose should be taken only if the next scheduled dose is at least 72 hours away**
  - A double dose should not be taken to make up for the missed dose
  - If vomiting occurs after taking a dose, the patient should not repeat the dose. The patient should resume dosing at the time of the next scheduled dose
- **Antiviral prophylaxis should be considered in patients being treated with NINLARO to decrease the risk of herpes zoster reactivation**

## Considerations prior to initiating a new cycle of therapy<sup>1</sup>

- Absolute neutrophil count should be at least 1000/mm<sup>3</sup>
- Platelet count should be at least 75,000/mm<sup>3</sup>. Monitor platelet counts at least monthly during treatment with NINLARO
- Nonhematologic toxicities should, at the healthcare provider's discretion, generally be recovered to patient's baseline condition or grade 1 or lower



### Communication is key

- There's no such thing as overcommunicating
- To verify comprehension, have patients repeat information in their own words

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib) full Prescribing Information.

## Storage<sup>1</sup>

- NINLARO® (ixazomib) may be stored at room temperature. Do not store above 30°C (86°F). Do not freeze
- Store capsules in original packaging until immediately prior to use

## Handling and disposal<sup>1</sup>

- NINLARO is cytotoxic. Capsules should not be opened, crushed, or chewed. Direct contact with the capsule contents should be avoided
- NINLARO is available in single dose packs (1 pill) and complete monthly dose packs (3 pills)
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements



### Capsule breakage<sup>1</sup>

- In case of capsule breakage, avoid direct contact of capsule contents with the skin or eyes. If skin contact occurs, wash thoroughly with soap and water. If contact occurs with the eyes, flush thoroughly with water

## Capsule warnings<sup>1</sup>



Capsule should not be crushed



Capsule should not be chewed



Capsule should not be opened



Capsule should not be removed from original packaging until time of consumption

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib) full Prescribing Information.



## Nonhematologic ARs occurring in $\geq 5\%$ of patients between the NINLARO® (ixazomib) regimen\* and

## with a $\geq 5\%$ difference the Rd regimen<sup>1\*</sup>

AR	NINLARO regimen (n=360)		
	All grades	Grade 3	Grade 4
Diarrhea	42%	6%	0
Constipation	34%	<1%	0
Peripheral neuropathies <sup>†</sup>	28%	2%	0
Nausea	26%	2%	0
Peripheral edema	25%	2%	0
Vomiting	22%	1%	0
Back pain	21%	<1%	0
Upper respiratory tract infection	19%	<1%	0
Rash <sup>†</sup>	19%	3%	0

Rd regimen (n=360)			Difference
All grades	Grade 3	Grade 4	All grades
36%	2%	0	6%
25%	<1%	0	9%
21%	2%	0	7%
21%	0	0	5%
18%	1%	0	7%
11%	<1%	0	11%
16%	3%	0	5%
14%	<1%	0	5%
11%	1%	0	8%

\*The NINLARO regimen included NINLARO+lenalidomide+dexamethasone. The Rd regimen included placebo+lenalidomide+dexamethasone.

<sup>†</sup>Represents a pooling of preferred terms.

### Additional safety information<sup>1</sup>

- Serious ARs reported in  $\geq 2\%$  of patients included thrombocytopenia (2%) and diarrhea (2%)

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib)

10 full Prescribing Information.



## Hematologic adverse events<sup>1</sup>

	NINLARO® (ixazomib) regimen* (n=360)		Rd regimen* (n=360)	
	n (%)		n (%)	
	Any grade	Grades 3-4	Any grade	Grades 3-4
Thrombocytopenia	281 (78)	93 (26)	196 (54)	39 (11)
Neutropenia	240 (67)	93 (26)	239 (66)	107 (30)

Represents pooled information from adverse event and laboratory data.

## Discontinuation rates

Discontinuation rates were comparable between the NINLARO® (ixazomib) and Rd regimens<sup>5\*</sup>

Discontinuation rates of the entire regimen due to ARs

**13%**  
VS  
**11%**

with the NINLARO and Rd regimens, respectively

Dose tolerability

**80%**

of patients continued at the starting dose of NINLARO without dose reduction

- For each AR, 1 or more of the 3 drugs were discontinued in ≤1% of patients in the NINLARO regimen<sup>1</sup>
- The median time on therapy for patients in the NINLARO arm was 17 cycles compared with 15 cycles for patients in the Rd arm<sup>6</sup>
- The most common ARs (≥20%) in the NINLARO regimen and greater than the Rd regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious ARs reported in ≥2% of patients included thrombocytopenia (2%) and diarrhea (2%)<sup>1</sup>

\*The NINLARO regimen included NINLARO+lenalidomide+dexamethasone. The Rd regimen included placebo+lenalidomide+dexamethasone.

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib)

12 full Prescribing Information.

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## Prepare patients for side effects and dosing concerns

Concomitant medications may be given for prophylaxis and/or management of symptoms<sup>7,8</sup>

Condition	Prophylaxis/symptomatic	Consider*
GI toxicity: diarrhea	Symptomatic	Antidiarrheal (eg, loperamide)
GI toxicity: nausea/vomiting	Prophylaxis or symptomatic	Antiemetics, anti-nauseants (eg, ondansetron, metoclopramide)
Viral infection: herpes zoster (reactivation)	Prophylaxis <sup>†</sup> or symptomatic	Antivirals <sup>†</sup>
Rash	Prophylaxis or symptomatic	Antihistamines (eg, cetirizine) or corticosteroids (oral or topical; eg, prednisone)

\*These medications and supportive therapies are examples of appropriate supportive care that were permitted in the phase 3 clinical trial.<sup>6</sup>

<sup>†</sup>Patients treated in the NINLARO regimen who received antiviral prophylaxis had a lower incidence (<1%) of herpes zoster infection compared with patients who did not receive prophylaxis (6%).<sup>7</sup>






Encourage patients and caregivers to report any side effects early so appropriate management measures can be taken.

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib)

14 full Prescribing Information.

## Management of some ARs may require modification of the NINLARO dose<sup>1</sup>

### NINLARO dose modification schedule

<b>4 mg</b> 	Recommended starting dose
<b>3 mg</b> 	First dose reduction Recommended starting dose for patients with: <ul style="list-style-type: none"> <li>• Moderate or severe hepatic impairment<sup>†</sup></li> <li>• Severe renal impairment<sup>‡</sup></li> <li>• End-stage renal disease requiring dialysis</li> </ul>
<b>2.3 mg</b> 	Second dose reduction
<b>If toxicities continue</b>	Discontinuation

Not actual capsule size.

- No dose adjustment is required for:
  - Elderly patients
  - Patients with mild to moderate renal impairment<sup>‡</sup>
  - Patients with mild hepatic impairment<sup>†</sup>
- NINLARO can be taken if patient is on dialysis

<sup>†</sup>Hepatic impairment: mild, total bilirubin  $\leq 1.5 \times$  ULN; moderate, total bilirubin  $>1.5$ - $3 \times$  ULN; severe, total bilirubin  $>3 \times$  ULN.

<sup>‡</sup>Renal impairment: mild to moderate, creatinine clearance  $\geq 30$  mL/min; severe, creatinine clearance  $<30$  mL/min.

ULN=upper limit of normal.


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## Dose modification guidelines for the NINLARO® (ixazomib) regimen<sup>1\*</sup>

### Hematological toxicities Recommended actions

#### Thrombocytopenia (platelet count)

- |  |  |
|--|--|
| Platelet count <30,000/mm <sup>3</sup> | <ul style="list-style-type: none"><li>• Withhold NINLARO and lenalidomide until platelet count is at least 30,000/mm<sup>3</sup></li><li>• Following recovery, resume lenalidomide at the next lower dose according to its Prescribing Information and resume NINLARO at its most recent dose</li><li>• If platelet count falls to &lt;30,000/mm<sup>3</sup> again, withhold NINLARO and lenalidomide until platelet count is at least 30,000/mm<sup>3</sup></li><li>• Following recovery, resume NINLARO at the next lower dose and resume lenalidomide at its most recent dose<sup>1</sup></li></ul> |
|--|--|

► **The first dose modification step for overlapping hematologic toxicities is to reduce the lenalidomide dose after withholding NINLARO and lenalidomide<sup>1</sup>**

- Refer to the lenalidomide Prescribing Information for the dose reduction steps for these toxicities

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib)

16 full Prescribing Information.

### Hematological toxicities Recommended actions

#### Neutropenia (absolute neutrophil count)

- |  |  |
|--|--|
| Absolute neutrophil count <500/mm <sup>3</sup> | <ul style="list-style-type: none"><li>• Withhold NINLARO and lenalidomide until absolute neutrophil count is at least 500/mm<sup>3</sup>. Consider adding G-CSF as per clinical guidelines</li><li>• Following recovery, resume lenalidomide at the next lower dose according to its Prescribing Information and resume NINLARO at its most recent dose</li><li>• If absolute neutrophil count falls to &lt;500/mm<sup>3</sup> again, withhold NINLARO and lenalidomide until absolute neutrophil count is at least 500/mm<sup>3</sup></li><li>• Following recovery, resume NINLARO at the next lower dose and resume lenalidomide at its most recent dose<sup>1</sup></li></ul> |
|--|--|

\*The NINLARO regimen includes NINLARO+lenalidomide+dexamethasone.

<sup>1</sup>For additional occurrences, alternate dose modification of lenalidomide and NINLARO. G-CSF=granulocyte-colony stimulating factor.

## Dose modification guidelines for the NINLARO® (ixazomib) regimen<sup>1\*</sup> (cont'd)

### Nonhematological toxicities

#### Rash

Grade	Recommended actions
Grade <sup>2</sup> 2 or 3	<ul style="list-style-type: none"> <li>Withhold lenalidomide until rash recovers to grade 1 or lower</li> <li>Following recovery, resume lenalidomide at the next lower dose according to its Prescribing Information</li> <li>If grade 2 or 3 rash occurs again, withhold NINLARO and lenalidomide until rash recovers to grade 1 or lower</li> <li>Following recovery, resume NINLARO at the next lower dose and resume lenalidomide at its most recent dose<sup>4</sup></li> </ul>
Grade 4	<ul style="list-style-type: none"> <li>Discontinue treatment regimen</li> </ul>

#### Peripheral neuropathy

Grade 1 peripheral neuropathy with pain or grade 2 peripheral neuropathy	<ul style="list-style-type: none"> <li>Withhold NINLARO until peripheral neuropathy recovers to grade 1 or lower without pain or patient's baseline</li> <li>Following recovery, resume NINLARO at its most recent dose</li> </ul>
Grade 2 peripheral neuropathy with pain or grade 3 peripheral neuropathy	<ul style="list-style-type: none"> <li>Withhold NINLARO. Toxicities should, at the healthcare provider's discretion, generally recover to patient's baseline condition or grade 1 or lower prior to resuming NINLARO</li> <li>Following recovery, resume NINLARO at the next lower dose</li> </ul>
Grade 4 peripheral neuropathy	<ul style="list-style-type: none"> <li>Discontinue treatment regimen</li> </ul>

### Other nonhematological toxicities

Other grade 3 or 4 nonhematological toxicities

### Recommended actions

- Withhold NINLARO. Toxicities should, at the healthcare provider's discretion, generally recover to patient's baseline condition or grade 1 or lower prior to resuming NINLARO
- If attributable to NINLARO, resume NINLARO at the next lower dose following recovery

#### Rash maculo-papular<sup>9</sup>

Grade 2: macules/papules covering 10%–30% body surface area (BSA) with or without symptoms (eg, pruritus, burning, tightness); limiting instrumental activities of daily living (ADL); rash covering >30% BSA with or without mild symptoms.

Grade 3: macules/papules covering >30% BSA with moderate or severe symptoms; limiting self-care ADL.

#### Peripheral sensory neuropathy<sup>9</sup>

Grade 1: asymptomatic.

Grade 2: moderate symptoms; limiting instrumental ADL.

Grade 3: severe symptoms; limiting self-care ADL.

Grade 4: life-threatening consequences; urgent intervention indicated.

### ► The first dose modification step for overlapping toxicities of rash is to withhold/reduce lenalidomide

\*The NINLARO regimen includes NINLARO+lenalidomide+dexamethasone.

<sup>1</sup>Grading based on National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03.

<sup>4</sup>For additional occurrences, alternate dose modification of lenalidomide and NINLARO.



### Provide patients with close follow-up support

- Encourage patients to report any side effects as they occur so the appropriate management measures can be taken

Please see Important Safety Information on pages 20-21 and accompanying NINLARO (ixazomib) full Prescribing Information.

For additional information regarding lenalidomide and dexamethasone, please see their Prescribing Information.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO® (ixazomib). 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. Adjust dosing as needed. Platelet nadirs typically occurred between Days 14-21 of each 28-day cycle and recovered to baseline by the start of the next cycle.
- **Gastrointestinal Toxicities**, including diarrhea, constipation, nausea and vomiting, were reported with NINLARO and may occasionally require the use of anti-diarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for severe symptoms.
- **Peripheral Neuropathy** (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% 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 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.
- **Peripheral Edema** was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.
- **Cutaneous Reactions**: 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.
- **Thrombotic Microangiopathy**: Cases, sometimes fatal, 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.

Please see accompanying  
NINLARO (ixazomib)

20 full Prescribing Information.



### WARNINGS AND PRECAUTIONS (cont'd)

- **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. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.
- **Embryo-fetal Toxicity**: 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 final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with NINLARO and for 90 days following the final dose. NINLARO can cause fetal harm.

### ADVERSE REACTIONS

The most common adverse reactions ( $\geq 20\%$ ) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in  $\geq 2\%$  of patients included thrombocytopenia (2%) and diarrhea (2%).

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

### SPECIAL POPULATIONS

- **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.
- **Lactation**: Advise women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.

**REFERENCES**: 1. NINLARO. Prescribing information. Takeda Pharmaceutical Company, Limited; 3/2021. 2. Revlimid. Prescribing information. Celgene Corporation; 10/2019. 3. Dexamethasone. Package insert. Roxane Laboratories, Inc; 2/2015. 4. McCue DA, Lohr LK, Pick AM. Improving adherence to oral cancer therapy in clinical practice. *Pharmacotherapy*. 2014;34(5):481-494. 5. Data on File. Takeda Pharmaceutical Company Limited; 2021. 6. Moreau P, Masszi T, Grzasko N, et al; for TOURMALINE-MM1 Study Group. Oral ixazomib, lenalidomide, and dexamethasone for multiple myeloma. *N Engl J Med*. 2016;374(17):1621-1634. 7. Kumar S, Moreau P, Hari P, et al. Management of adverse events associated with ixazomib plus lenalidomide/dexamethasone in relapsed/refractory multiple myeloma. *Br J Haematol*. 2017;178(4):571-582. 8. Kumar SK, Vij R, Noga SJ, et al. Treating multiple myeloma patients with oral therapies. *Clin Lymphoma Myeloma Leuk*. 2017;17(5):243-251. 9. US Department of Health and Human Services. *Common Terminology Criteria for Adverse Events (CTCAE)*. Version 5.0. Published November 27, 2017.



# NINLARO® (ixazomib): What you need to know

## Dosing<sup>1</sup>

- The recommended starting dose of NINLARO is 4 mg (one capsule) in combination with lenalidomide and dexamethasone
- NINLARO is available in 3 capsule strengths

## Schedule<sup>1</sup>

- NINLARO is taken once a week for the first 3 weeks of a 4-week cycle
- Treatment should be continued until disease progression or unacceptable toxicity

## 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.

## Adverse Reactions

The most common adverse reactions ( $\geq 20\%$ ) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%); pooled from adverse events and laboratory data, peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in  $\geq 2\%$  of patients included thrombocytopenia (2%) and diarrhea (2%).

## CONTACT US FOR ADDITIONAL INFORMATION

Visit [www.here2assist.com](http://www.here2assist.com)

Phone: 1-844-817-6468

Select option 1 for medical information.

Select option 2 for support.

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