



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 260936 NINLARO ixazomib (as citrate) 2.3mg capsule blister pack

**ARTG entry for** Medicine Registered  
**Sponsor** Takeda Pharmaceuticals Australia Pty Ltd  
**Postal Address** GPO Box 2728, Sydney, NSW, 2001  
 Australia  
**ARTG Start Date** 15/11/2016  
**Product category** Medicine  
**Status** Active  
**Approval area** Drug Safety Evaluation Branch

**Conditions**

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

**Products**

**1. NINLARO ixazomib (as citrate) 2.3mg capsule blister pack**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	15/11/2016
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

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.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/Al	3 Years	Store below 30 degrees Celsius	Not recorded	Do not Freeze

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
3 capsules	(S4) Prescription Only Medicine
1 capsule	(S4) Prescription Only Medicine

**Components**

**1. NINLARO ixazomib (as citrate) 2.3mg capsule blister pack**

<b>Dosage Form</b>	Capsule
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Light pink gelatin capsule imprinted with the Takeda logo on the cap and 2.3 mg on the body, in black ink

**Active Ingredients**

ixazomib citrate	<b>3.29 mg</b>
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