NINLARO® Approved Patient Information Leaflet

SCHEDULING STATUS

S4

NINLARO® 2,3 mg light pink hard capsules

NINLARO® 3 mg light grey hard capsules

NINLARO® 4 mg light orange hard capsules

Read all of this leaflet carefully before you start taking NINLARO®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **NINLARO®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms

  are the same as yours.

What is in this leaflet

1. What **NINLARO®** is and what it is used for
2. What you need to know before you take **NINLARO®**
3. How to take **NINLARO®**
4. Possible side effects
5. How to store **NINLARO®**
6. Contents of the pack and other information

1. What NINLARO® is and what it is used for

What NINLARO® is

NINLARO® is a cancer medicine that contains ixazomib, a 'proteasome inhibitor'. **NINLARO®** is used to treat a cancer of the bone marrow called multiple myeloma. Its active substance ixazomib works by blocking the action of proteasomes. These are structures inside the cell that digest proteins and are important for cell

survival. Because myeloma cells produce a lot of proteins, blocking the action of proteasomes can kill the cancerous cells.

What NINLARO® is used for

NINLARO® is used to treat adults with multiple myeloma. **NINLARO®** will be given to you together with lenalidomide and dexamethasone, which are other medicines used to treat multiple myeloma.

What multiple myeloma is

Multiple myeloma is a cancer of the blood which affects a type of cell, called the plasma cell. A plasma cell is a blood cell that normally produces proteins to fight infections. People with multiple myeloma have cancerous plasma cells, also called myeloma cells, which can damage the bones. Protein produced by myeloma cells can damage the kidneys. Treatment for multiple myeloma involves killing myeloma cells and reducing the symptoms of the disease.

2. What you need to know before you take NINLARO®

Do not take NINLARO®

if you are allergic to ixazomib or to any of the other ingredients of this medicine (listed in section 6).

If you are uncertain whether the condition above applies to you, talk to your doctor, pharmacist or nurse before taking **NINLARO®**.

Warnings and precautions

Talk to your doctor or healthcare provider before taking or during treatment with NINLARO® if:

- you have a history of bleeding
- you have persistent nausea, vomiting or diarrhoea
- you have a history of nerve problems, which include tingling and numbness
- you have a history of swelling
- you have a persistent rash or a severe skin rash with skin peeling and mouth sores (Stevens Johnson syndrome or toxic epidermal necrolysis, see section 4)
- you have a persistent rash
- you have or have had liver or kidney problems as your dose may have to be adjusted.
- you have or have had damage to the smallest blood vessels known as thrombotic microangiopathy or thrombotic thrombocytopenic purpura. Tell your doctor if you develop fatigue, fever, bruising, bleeding, decreased urination, swelling, confusion, vision loss, and seizures.

Your doctor will examine you and you will be monitored closely during treatment.

Before starting **NINLARO®** and during treatment, you will have blood tests to check that you have enough blood cells.

Children and adolescents

NINLARO® is not recommended for use in children and adolescents aged under 18 years of age.

Other medicines and NINLARO®

Tell your health care provider if you are taking, have recently taken or might take any other medicines. This includes any medicines obtained without a prescription, such as vitamins or herbal remedies. This is because other medicines can affect the way **NINLARO®** works. In particular, tell your health care provider if you are taking any of the following medicines: carbamazepine, phenytoin, rifampicin and St. John's wort (Hypericum perforatum).

These medicines should be avoided as they may reduce the effectiveness of **NINLARO®**.

Pregnancy, breast-feeding and fertility

NINLARO® must not be used during pregnancy as it may harm your unborn baby.

Mothers taking **NINLARO®** must not breast-feed their infants.

Avoid becoming pregnant or breast-feeding while being treated with **NINLARO®**. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or health care provider for advice.

If you are a woman of childbearing potential or a man who can father a child, you must use effective contraception during and for 90 days after treatment.

Women using hormonal contraceptives should additionally use a barrier method of contraception.

Tell your doctor right away if you or your partner becomes pregnant while receiving **NINLARO®**

As **NINLARO®** is given in combination with lenalidomide, you should also adhere to the pregnancy prevention program of lenalidomide because lenalidomide can be harmful to the unborn child

Driving and using machines

NINLARO® may affect your ability to drive or use machines. You may feel tired and dizzy while taking **NINLARO®**. Do not drive or operate machines if you have these side effects.

It is not always possible to predict to what extent **NINLARO®** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the level to which **NINLARO®** affects you.

3. How to take NINLARO®

Do not share medicines provided for you with any other person.

NINLARO® must be prescribed to you by a doctor with experience of treating multiple myeloma. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or health care provider if you are not sure or have the impression that the effect of **NINLARO®** is too strong for you.

NINLARO® is used with lenalidomide (a medicine which affects how your immune system works) and dexamethasone (an anti-inflammatory medicine).

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NINLARO®, lenalidomide and dexamethasone are taken in 4-week treatment cycles.

NINLARO® is taken once a week (on the same day of the week) for the first 3 weeks of this cycle. The recommended dose is one 4 mg capsule taken by mouth.

Dosing Schedule: NINLARO® taken with lenalidomide and dexamethasone

28-Day Cycle (a 4-week cycle)								
	Week 1		**Week 2**		**Week 3**		**Week 4**	
	Day 1	Days 2 to 7	Day 8	Days 9 to 14	Day 15	Days 16 to 21	Day 22	Days 23 to 28
NINLARO®	√		√		√			
Lenalidomide	√	√Daily	√	√Daily	√	√Daily		
Dexamethasone	√		√		√		√	

√ intake of medicinal product

You should read the Professional information of these other medicines for further information on their use and effects.

If you have liver or kidney problems, your doctor may prescribe **NINLARO®** capsules containing 3 mg. If you have side effects, your doctor may prescribe **NINLARO®** capsules containing 3 mg or 2,3 mg. The doctor may also adjust the doses of the other medicines.

How and when to take NINLARO®

- Take **NINLARO®** at least one hour before or at least two hours after food.
- Swallow the capsule whole with water. Do not crush, chew or open the capsule.
- Do not let the contents of the capsule come into contact with your skin. If the powder accidentally comes into contact with your skin, wash it off thoroughly with soap and water. If the capsule breaks, clean up the powder, taking care that it does not cause dust in the air.

If you take more NINLARO® than you should

Accidental overdose can cause serious side effects. If you take more **NINLARO®** than you should, talk to a doctor immediately or go to a hospital straight away. Take the medicine pack with you.

Duration of the treatment with NINLARO®

You should continue treatment until your doctor tells you to stop.

If you forget to take NINLARO®

If a dose is missed or delayed, you should take the dose as long as the next scheduled dose is more than 3 days or 72 hours away. Do not take a missed dose if it is within 3 days or 72 hours of your next scheduled dose. If you vomit after taking a dose, do not take an extra dose. Take the next dose, as normal, when it is due. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or health care provider

4. Possible side effects

NINLARO® can have side effects.

Not all side-effects reported for NINLARO® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **NINLARO®,** please consult your health care provider immediately for advice.

Stop using NINLARO® and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis, which may affect up to 1 in 1,000 people).

Tell your doctor or pharmacist straight away if you notice any of the following very serious side effects:

- low platelet counts (thrombocytopaenia) which may increase the risk of nose bleeds and you may bruise easily.
- nausea, vomiting and diarrhoea
- numbness, tingling or burning of the hands or feet (peripheral neuropathy)
- swelling of the legs or feet (peripheral oedema)
- skin rash that may be itchy and appears in a few areas or all over the body
- cough, chest soreness or pain, or nasal congestion (bronchitis)

Additionally, tell a doctor immediately if you notice any of these following less frequent side effects:

- severe skin rashes such as red to purple bumps (Sweet's syndrome)
- muscle weakness, loss of feelings of the toes and feet or loss of leg movement (transverse myelitis)
- hanges in vision, changes in mental status, or seizures (posterior reversible encephalopathy syndrome)

- rapid death of cancer cells that may cause dizziness, decreased urination, confusion, vomiting, nausea, swelling, shortness of breath, or heart rhythm disturbances (tumour lysis syndrome)
- rare blood condition resulting from blood clots that may cause fatigue, fever, bruising, bleeding e.g.nose bleeds, decreased urination. swelling, confusion, vision loss, and seizures (thrombotic microangiopathy, (thrombotic thrombocytopenic purpura)
- swelling of the face, lips, tongue or throat, trouble breathing or swallowing, wheezing, chest tightness or dizziness, skin itching and hives (angioedema or anaphylactic reaction)

Other possible side effects

Tell your doctor or pharmacist if any of the side effects below become severe.

Frequent side effects:

- constipation
- back pain
- cold-like symptoms (upper respiratory tract infection)
- feeling tired or weak (fatigue)
- fever (pyrexia)
- joint pain (arthralgia)
- lowered white blood cells called neutrophils (neutropenia) that may increase the risk of infection
- not feeling like eating (decreased appetite)
- irregular heartbeats (dysrhythmia)
- vision conditions including blurred vision, dry eye and pink eye (conjunctivitis)

Less frequent side effects:

- reactivation of the chicken pox virus (shingles) that can cause a skin rash and pain (herpes zoster)
- lowered blood pressure (hypotension)
- shortness of breath or persistent coughing or wheezing (heart failure)
- yellow discoloration of eyes and skin (jaundice which could be a symptom of liver impairment)
- low levels of potassium in the blood (hypokalaemia)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or health care provider.

This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. Additionally, suspected adverse reactions can be reported to AE.southafricassa@takeda.com or on the 24 hours contact number: 082 525 3040.

By reporting side effects, you can help provide more information on the safety of **NINLARO®**.

5. How to store NINLARO®

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister, wallet and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 30° C. Do not freeze. Do not store in a bathroom.
Store in the original package in order to protect from moisture.
Do not remove the capsule until you need to take a dose.
Do not use this medicine if you notice any damage or signs of tampering to medicine packaging.
Do not dispose of unused medicines in drains or sewerage systems (e.g toilets). Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What NINLARO® contains

NINLARO® 2,3 mg hard capsule:

- The active substance is ixazomib. Each capsule contains 2.3 mg of ixazomib (as 3,3 mg of ixazomib citrate).

The other ingredients are:

- In the capsule: microcrystalline cellulose, magnesium stearate and talc.
- The capsule shell contains: gelatin, titanium dioxide (E171) and red iron oxide (E172).
- The printing ink contains: shellac, propylene glycol, potassium hydroxide, and black iron oxide (E172).

NINLARO® 3 mg hard capsule:

- The active substance is ixazomib. Each capsule contains 3 mg of ixazomib (as 4,3 mg of ixazomib citrate).

The other ingredients are:

- In the capsule: microcrystalline cellulose, magnesium stearate and talc.
- The capsule shell contains: gelatin, titanium dioxide (E171) and black iron oxide (E172)
- The printing ink contains: shellac, propylene glycol, potassium hydroxide, and black iron oxide (E172)

NINLARO® 4 mg hard capsule:

- The active substance is ixazomib. Each capsule contains 4 mg of ixazomib (as 5,7 mg of ixazomib citrate).

The other ingredients are:

- In the capsule: microcrystalline cellulose, magnesium stearate and talc.
- The capsule shell contains: gelatin, titanium dioxide (E171), yellow iron oxide (E172) and red iron oxide (E172)
- The printing ink contains: shellac, propylene glycol, potassium hydroxide, and black iron oxide (E172)

What NINLARO® looks like and contents of the pack

NINLARO® 2,3 mg hard capsule: Light pink, size 4, marked “Takeda” on the cap and “2,3 mg” on the body with black ink.

NINLARO® 3 mg hard capsule: Light grey, size 4, marked “Takeda” on the cap and “3 mg” on the body with black ink.

NINLARO® 4 mg hard capsule: Light orange, size 3, marked “Takeda” on the cap and “4 mg” on the body with black ink.

Each pack contains 3 hard capsules (Three blisters sealed within the blister strip inside a wallet. Each blister contains one capsule).

Holder of Certificate of Registration

TAKEDA (Pty) Ltd

Building A, Monte Circle

64 Montecasino Boulevard

Fourways

2191

Tel: +27 11 514 3000

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