

Ninlaro[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ninlaro?

Ninlaro contains the active ingredient ixazomib citrate. Ninlaro is used to treat patients with a type of cancer of the bone marrow called multiple myeloma. It is used in people who have received at least one prior multiple myeloma treatment.

For more information, see Section [1. Why am I using Ninlaro?](#) in the full CMI.

2. What should I know before I use Ninlaro?

Do not use if you have ever had an allergic reaction to Ninlaro or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ninlaro?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ninlaro and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ninlaro?

- Ninlaro is used with two other medicines called lenalidomide (a medicine which affects how your immune system works) and dexamethasone (an anti-inflammatory medicine).
- Ninlaro, lenalidomide and dexamethasone are taken in 4 week (28 days) treatment cycles.

More instructions can be found in Section [4. How do I use Ninlaro?](#) in the full CMI.

5. What should I know while using Ninlaro?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Ninlaro.• Read this leaflet carefully before you start
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	<p>using this medicine. It contains important information for you.</p> <ul style="list-style-type: none"> ● Keep this leaflet. You may need to read it again. ● Be sure to keep all your doctor's appointments so your progress can be checked.
Things you should not do	<ul style="list-style-type: none"> ● Do not change your dose or stop taking Ninlaro without talking to your doctor first.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how Ninlaro affects you.
Looking after your medicine	<ul style="list-style-type: none"> ● Keep the medicine in a cool, dry place where the temperature stays below 30°C. Do not freeze. ● Store capsules in the original packaging until just prior to dosing.

For more information, see Section [5. What should I know while using Ninlaro?](#) in the full CMI.

6. Are there any side effects?

Common side effects include nausea, vomiting, constipation, numbness, tingling or burning of the hands or feet, weakness in your arms or legs, swelling of the legs or feet, back pain, skin rash that may be itchy and in a few areas or all over the body, cold-like symptoms (upper respiratory tract infection), reactivation of the chicken pox virus (shingles) that can cause a skin rash and pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ninlaro[®]

Active ingredient(s): *ixazomib citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ninlaro. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ninlaro.**

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.takeda.com/en-au. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

- [1. Why am I using Ninlaro?](#)
- [2. What should I know before I use Ninlaro?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ninlaro?](#)
- [5. What should I know while using Ninlaro?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Ninlaro?

Ninlaro contains the active ingredient ixazomib citrate. Ninlaro belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. These medicines are used to kill cancer cells.

Ninlaro is used with two other prescription medicines called lenalidomide and dexamethasone.

Ninlaro is used to treat patients with a type of cancer of the bone marrow called multiple myeloma. It is used in people who have received at least one prior multiple myeloma treatment.

Multiple myeloma is a cancer of the blood which affects a certain type of cell, called the plasma cell.

A plasma cell is a type of 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 also damage the kidneys. Treatment for multiple myeloma involves trying to kill myeloma cells and reduce the symptoms of the disease.

2. What should I know before I use Ninlaro?

Warnings

Do not use Ninlaro if:

- you are allergic to ixazomib citrate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not give Ninlaro to a child under the age of 18 years. Ninlaro is not recommended for use in children and young people under 18 years.
- Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering. If it has expired or is damaged return it to your pharmacist for disposal.

Check with your doctor if you:

- have or have had any of the following medical conditions
 - history of bleeding
 - persistent nausea, vomiting and/or diarrhoea
 - liver or kidney problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to get pregnant, ask your doctor for advice before taking this medicine.

Avoid becoming pregnant while being treated with Ninlaro. Ninlaro may harm your unborn baby.

Both men and women receiving Ninlaro must use effective contraception during and for up to three months (90 days) after treatment.

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

Tell your doctor immediately if you or your partner become pregnant while you are taking this medicine.

If you are breastfeeding or plan to breastfeed, ask your doctor for advice before taking this medicine.

It is not known if Ninlaro passes into breast milk.

Do not breastfeed during treatment with Ninlaro.

Ninlaro is used in combination with lenalidomide. Refer to the lenalidomide Consumer Medicine Information for serious warnings about lenalidomide use during pregnancy.

If you have not told your doctor about any of the above, tell him/her before you take Ninlaro.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Ninlaro and affect how it works.

Medicines that may reduce the effect of Ninlaro include:

- carbamazepine
- phenytoin
- rifampicin and
- St. John's wort (*Hypericum perforatum*)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ninlaro.

4. How do I use Ninlaro?

How much to take

- Follow the instructions provided and use Ninlaro until your doctor tells you to stop.
- The recommended dose is one 4 mg capsule taken by mouth.

- The recommended dose of lenalidomide is 25 mg taken every day for the first 3 weeks of the cycle.
- The recommended dose of dexamethasone is 40 mg taken once a week on the same day for all 4 weeks of the cycle.
- 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.
- Your doctor may also adjust the doses of the other medicines.
- Please see dosing schedule table at the end of this leaflet.

When to take Ninlaro

- Ninlaro is taken once a week (on the same day of the week and at approximately the same time) for the first 3 weeks of the cycle.
- Ninlaro should be taken at least one hour before or at least two hours after food. Food can interfere with this medicine.
- You should continue the cycles of treatment until your doctor tells you to stop.

How to take Ninlaro

- Swallow the capsule whole with water.
- Do not crush, chew or open the capsule.
- Do not come into direct contact with the capsule contents.

- In case of capsule breakage, do not raise dust during clean-up. If contact occurs, wash skin thoroughly with soap and water.

If you forget to use Ninlaro

Ninlaro is taken once a week (on the same day of the week and at approximately the same time) for the first 3 weeks of the cycle.

If a dose is missed or delayed, you should take the dose as long as the next scheduled dose is more than 3 days (72 hours) away.

Do not take a missed dose if it is within 3 days (72 hours) of your next scheduled dose.

Do not take a double dose to make up for the dose you missed.

If you vomit after taking a dose, do not repeat the dose but resume dosing at the time of the next scheduled dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much Ninlaro

If you think that you have used too much Ninlaro, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Ninlaro?

Things you should do

Be sure to keep all your doctor's appointments so your progress can be checked.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ninlaro.

If you become pregnant or your partner becomes pregnant while you are taking Ninlaro, tell your doctor immediately.

Things you should not do

- Do not change your dose or stop taking Ninlaro without talking to your doctor first.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ninlaro affects you.

There is no information on the effect of Ninlaro on the ability to drive or use machines.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- Keep your capsules in the pack until it is time to take them.
- Do not remove the capsule from the blister until just before taking it.
- Keep the medicine in a cool, dry place where the temperature stays below 30°C. Do not freeze.
- Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car. Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

If your doctor tells you to stop taking this medicine, or the medicine has passed its expiry date, return it to your pharmacist for disposal.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not throw away via wastewater or household waste.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nausea• vomiting• constipation• numbness, tingling or burning of the hands or feet, weakness in your arms or legs• swelling of the legs or feet	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● back pain ● skin rash that may be itchy and in a few areas or all over the body ● cold-like symptoms (upper respiratory tract infection) ● reactivation of the chicken pox virus (shingles) that can cause a skin rash and pain 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● (bleeding or bruising more easily than normal. This could be a sign of low blood platelet count ● Diarrhoea ● Fatigue, fever, bruising, bleeding, decreased urination, swelling, confusion, vision loss, and seizures. This could be a sign of damage to the 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>smallest blood vessels known as thrombotic microangiopathy</p> <ul style="list-style-type: none"> • severe skin rash with skin peeling and mouth sores (Stevens Johnson syndrome) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ninlaro contains

<p>Active ingredient (main ingredient)</p>	<p>ixazomib citrate</p>
<p>Other ingredients (inactive ingredients)</p>	<p>microcrystalline cellulose magnesium stearate purified talc</p> <p>All capsule shells contain gelatin and titanium dioxide.</p> <p>The 4 mg capsule shell contains iron oxide red and iron oxide yellow, the 3 mg capsule shell contains iron oxide black and the 2.3 mg capsule shell contains iron oxide red.</p> <p>The capsules are imprinted with TekPrint SW-9008 Black Ink (ARTG PI No 2328).</p>

Do not take this medicine if you are allergic to any of these ingredients.

What Ninlaro looks like

4 mg capsule: light orange gelatin capsule imprinted with the Takeda logo on the cap and 4 mg on the body, in black ink (AUST R 260934).

3 mg capsule: light grey gelatin capsule imprinted with the Takeda logo on the cap and 3 mg on the body, in black ink (AUST R 260935).

2.3 mg capsule: light pink gelatin capsule imprinted with the Takeda logo on the cap and 2.3 mg on the body, in black ink (AUST R 260936).

Ninlaro is available in a multipack carton with 3 single cartons containing 1 capsule each.

Who distributes Ninlaro

Takeda Pharmaceuticals Australia Pty Ltd

Level 39

225 George Street

Sydney, NSW 2000

Australia

Tel: 1800 012 612

www.takeda.com/en-au

This leaflet was prepared in May 2022.

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Dosing Schedule: NINLARO taken with lenalidomide and dexamethasone

✓ Take medicine

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	✓		✓		✓		✓	