Ninlaro Hard Capsule

Ixazomib 2.3mg, 3mg and 4mg

What is in this leaflet

What Ninlaro is used for

Ninlaro is a prescription medicine used to treat multiple myeloma in combination with the medicines lenalidomide and dexamethasone, in people who have received at least one prior treatment for their multiple myeloma. It is not known if Ninlaro is safe and effective in children.

How Ninlaro works

Ninlaro is a proteasome inhibitor. Proteasomes are enzymes found in cells that help the cell break down old or unwanted proteins. These proteins are split into amino acids which can then be recycled to make new proteins. Cancer cells depend on the proteasome to provide this protein metabolism (turnover) function to regulate their growth and survival. Ninlaro disrupts a cancer cells' ability to survive by blocking the proteasome and disrupting protein metabolism. Myeloma cells may be uniquely sensitive to proteasome inhibitors because they make large amounts of protein (called M-protein) and need this recycling function to survive.
Laboratory and animal studies show that Ninlaro inhibits the growth of myeloma cells, including those that are resistant to Bortezomib and other anti-myeloma therapies. Ninlaro also induces myeloma cell death (apoptosis).

Before you use Ninlaro

- <u>When you must not use it</u>

You should not take Ninlaro if you are allergic to ixazomib or any of the other ingredients of this medicine.

- <u>Before you start to use it</u>

Before you take Ninlaro, tell your doctor if you**:**

- Have a history of bleeding
- Have persistent nausea, vomiting or diarrhoea
- Have a history of nerve problems, to include tingling and numbness
- Have a history of swelling
- Have a persistent rash or a severe skin rash with skin peeling and mouth sores (Stevens Johnson syndrome) or toxic epidermal necrolysis
- Have liver problems
- Have kidney problems or are on dialysis.
- 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.
- Are pregnant or plan to become pregnant. Ninlaro can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Ninlaro passes into breast milk. Do not breastfeed during treatment with Ninlaro.

- <u>Taking other medicines</u>

- Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Contact your doctor before you start or stop other types of medicines.
- Your doctor may prescribe a medicine to take with Ninlaro to decrease the risk of the chicken pox virus (herpes zoster) coming back (reactivation).

How to use Ninlaro

- <u>How much to use</u>

- Ninlaro is taken in "cycles". Each cycle lasts 4 weeks (28 days).
- The usual dose of Ninlaro is 1 capsule taken 1 time each week, on the same day of the week for the first 3 weeks of each cycle.
- Take lenalidomide and dexamethasone exactly as doctor tells you to.
- Swallow Ninlaro capsules whole with water, Do not crush, chew or open the capsule.

- <u>When to use it</u>

Take Ninlaro at least 1 hour before or at least 2 hours after food.
On the days that you take both Ninlaro and dexamethasone, do not take Ninlaro and dexamethasone at the same time. Take dexamethasone with food.

- <u>How long to use it</u>

Take Ninlaro exactly as your doctor tells you to take it.
Your doctor may change your dose or stop Ninlaro, lenalidomide or dexamethasone if you have side effects.

- <u>If you forget to use it</u>

If you miss a dose of Ninlaro, or if you are late taking a dose, take the dose as long as the next scheduled dose is more

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than 3 days (72 hours) away. Do not take a missed dose of Ninlaro if it is within 3 days (72 hours) of your next scheduled dose. If you do not remember until it is time for your next dose, skip the missed dose, and take the next dose at your regular time. Do not take two doses of Ninlaro at the same time.

- If you use too much (overdose)

- If you take more Ninlaro than your doctor tells you to take, call your doctor right away or go to the nearest hospital emergency room right away.
- If you vomit after taking a dose of Ninlaro, do not repeat the dose. Take you next dose of Ninlaro on the next scheduled day and time.

While you are using it

- Things you must do

- Females and males with female partner who are able to become pregnant must use effective birth control during treatment and for 90 days after your final dose of Ninlaro.
- Tell your doctor right away if you or your partner becomes pregnant while you are receiving Ninlaro.

- Things you must not do

- Avoid becoming pregnant during treatment with Ninlaro.
- Breastfeed or plan to breastfeed during treatment with Ninlaro and for 90days after your final dose of Ninlaro.

- Things to be careful of

Ninlaro is cytotoxic. Capsules should not be opened or crushed. Direct contact with the capsule contents should be avoided. In case of capsule breakage, avoid direct contact of capsule contents with the skin or eyes. If contact occurs with the skin, wash thoroughly with soap and water. If contact occurs with the eyes, flush thoroughly with water.

Side Effects

Ninlaro can cause serious side effects, including:

- Low platelet counts (thrombocytopenia): Low platelet counts are common with Ninlaro, and can sometimes be serious. You may need platelet transfusions if your counts are too low. Tell your doctor if you have signs of low platelet counts, including bleeding and easy bruising.
- Stomach and intestinal problems. Diarrhea, constipation, nausea, and vomiting are common with Ninlaro, and can sometimes be severe. Call your doctor if you get any of these symptoms and they do not go away during treatment with Ninlaro.
- Nerve problems. Nerve problems are common with Ninlaro and may also be severe. Tell your doctor if you get any new or worsening symptoms, including:
  - Tingling
  - Numbness
  - Pain
  - A burning feeling in your feet or hands
  - Weakness in your arms or legs
- Swelling. Swelling is common with Ninlaro and can sometimes be severe. Tell your doctor if you develop swelling in your arms, hands, legs, ankles, or feet, or if you gain weight from swelling.
- Cough, chest soreness or pain, or nasal congestion (bronchitis)
- Skin reactions. Tell your doctor if you get a new or worsening rash.
- Liver problems. Tell your doctor if you get these signs of a liver problem:
  - Yellowing of your skin or the whites of your eyes
  - Pain in your right upper stomach-area

Other common side effects:

- Back pain
- Skin rash and pain (shingles) as a result of reactivation of the chicken pox virus (herpes zoster)
- Lowered white blood cells called neutrophils that may increase risk of infection
- Vision conditions including blurred vision, dry eye and pink eye (conjunctivitis)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Ninlaro

- Storage

Do not store above 30°C. Do not freeze. Keep Ninlaro capsules in the original packaging until immediately prior to use.
Keep Ninlaro and all medicines out of the reach of children.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

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These measures will help protect the environment.

Product Description

- What it looks like

Ninlaro is supplied as immediate release hard gelatin capsule and are distinguished both by colours and dose specific imprinted markings on the body:

- 2.3mg – light pink gelatin capsule imprinted with "Takeda" on the cap and "2.3mg" on the body in black ink.
- 3mg tablet – Light grey gelatin capsule imprinted with "Takeda" on the cap and "3.0mg" on the body in black ink.
- 4mg tablet – Light orange gelatin capsule imprinted with "Takeda" on the cap and "4.0mg" on the body in black ink.

- Ingredients
  - Active ingredient
    Ixazomib
  - Inactive ingredients

Microcrystalline cellulose, magnesium stearate and talc.

- MAL Number

MAL19126003ACRZ
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