

Ixazomib (Ninlaro)

About This Medicine

IXAZOMIB (ix az oh mib) treats multiple myeloma, a type of bone marrow cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Decrease in the number of white blood cells and platelets. This may raise your risk of infection and risk of bleeding.
- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Swelling in your legs, ankles, and/or feet
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the medicine. These effects get better in some people after the medicine is stopped but it does not get better in all people.
- Inflammation (swelling) in your airway
- Rash

Note: Each of the side effects above was reported in 20% or greater of patients treated with ixazomib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Severe decrease in the number of platelets
- · Severe diarrhea, constipation, nausea, and vomiting
- Severe swelling in your legs, ankles, and/or feet
- Severe peripheral neuropathy
- Changes in your liver function



- Severe rash and allergic skin reaction, which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Damage to small blood vessels, which can cause bleeding and blood clots and can be lifethreatening.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important Information

If you have had shingles (herpes zoster infection) before, it may come back. Symptoms of shingles
are burning or shooting pain and tingling or itching, often on one side of the body or face. The pain
can be mild to very bad.

How to Take Your Medicine

- Swallow the medicine whole with a glass of water. Do not crush, chew, or open the capsules.
- Take this medicine by mouth without food. Take at least 1 hour before you eat or at least 2 hours
 after you eat. Take at approximately the same time each time it is scheduled. Do not take it more
 often than directed.
- Do not take your dexamethasone at the same time you take ixazomib. Take dexamethasone with food and take ixazomib without food.
- **Missed dose:** If you miss a dose, and it is less than 72 hours until your next dose, then skip the missed dose and go back to your normal schedule. If you miss a dose, and it is more than or equal to 72 hours until your next dose, take it as soon as you think about it. Do not take 2 doses at the same time or extra doses. Do not replace a vomited dose.
- Overdosage: If you think you have taken too much of this medicine contact a poison control center
 or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- If you get any of the contents of a broken capsule on your skin or in your eyes, you should wash the area of the skin well with soap and water right away. Wash your eyes with flowing water for at least 15 minutes and call your care team. Call your care team if you get a skin reaction.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Do not store above 30°C (86°F). Do not freeze. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.



Treating Side Effects

- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a
 fever
- To decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- If you get any symptoms of shingles, call your care team right away. Do not put anything on it unless your care team says you may.

Food and Medicine Interactions

- There are no known interactions of ixazomib with food, however this medicine should be taken on an empty stomach.
- Check with your care team about all other prescription medicines and over-the-counter medicines
 and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this
 medicine as there are known medicine interactions with ixazomib. Also, check with your care team
 before starting any new prescription or over-the-counter medicines, or dietary supplements to make
 sure that there are no interactions.
- Avoid the use of St. John's Wort while taking ixazomib as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team



Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- · Easy bleeding or bruising
- · Blurred vision or other changes in eyesight,
- Dry eye and/or pink eye
- · Wheezing and/or trouble breathing
- · Coughing that is bothersome
- Nausea that stops you from eating or drinking, and/or that is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with weakness or a feeling of being dizzy
- No bowel movement for 3 days or when you feel uncomfortable
- · Numbness, tingling, or pain in your hands and feet
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling in your legs, ankles, and/or feet
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Signs of liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Decreased or very dark urine
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Signs of shingles such as burning or shooting pain and tingling or itching, often on one side of the body or face. The pain can be mild to very bad.
- If you think you are pregnant or may have impregnated your partner

Reproduction Warnings

- Pregnancy warning: This medicine can have harmful effects on the unborn baby. Women of child-bearing potential should use effective methods of birth control during your cancer treatment and for 90 days after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 90 days after stopping treatment. Let your care team know right away if you think you may be pregnant or may have impregnated your partner.
- Women using hormonal methods of birth control (i.e., birth control pills, skin patches, shots, vaginal rings, intrauterine devices (IUDs)) should also use a barrier methods of birth control such as a condom, sponge, diaphragm, spermicide, and/or cervical cap.
- **Breastfeeding warning**: Women should not breastfeed during treatment and for 90 days after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning**: Fertility studies have not been done with this medicine. Talk with your care team if you plan to have children. Ask for information on sperm or egg banking.



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