

# **Ixazomib** (Ninlaro)

### **About This Medicine**

Ixazomib is used to treat cancer. It is given orally (by mouth).

### **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 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 medical 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 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 medical 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, at least 1 hour before you eat or at least 2 hours after you eat, 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.
- **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 doctor. Call your doctor if you get a skin reaction
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic 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.
- **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 nurse or your doctor 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 doctor or nurse 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 nurse 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 doctor or nurse 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 doctor or nurse 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 nurse or doctor 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 doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- If you get any symptoms of shingles, call your doctor right away. Do not put anything on it unless your doctor or nurse 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 doctor or pharmacist 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
  doctor or pharmacist 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 the Doctor

Call your doctor or nurse 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 doctor 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 doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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