

Quizartinib (Vanflyta)

About This Medicine

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

Possible Side Effects

- Decrease in the number of white blood cells. This may raise your risk of infection.
- Neutropenic fever. A type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.
- Decrease in a blood protein called albumin
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Sepsis - a serious illness from an infection
- Headache
- Increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Electrolyte changes
- Changes in your liver function
- Upper respiratory tract infection

Note: Each of the side effects above was reported in greater than 20% of patients treated with quizartinib. 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

- Heart changes such as abnormal heartbeat and electrocardiogram (EKG/ECG) and cardiac arrest (your heart suddenly stops), which can be life-threatening.

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

- You will need to sign up for a special program called Vanflyta REMS when you start taking this medicine. Your nurse will help you get started.
- You will be given a Vanflyta Patient Wallet Card about the risk of heart problems that you should carry with you at all times during treatment. Show this card to any doctor or nurse who treats you.

How to Take Your Medicine

- Swallow the medicine whole, with or without food, at approximately the same time each day. Do not chew, cut, or crush it.
- **Missed dose:** If you miss a dose, take it as soon as you think about it on the same day.
- If you vomit a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **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.
- Drink plenty of fluids throughout the day.
- 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).
- 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.
- Ask your nurse or doctor about medicine that can lessen or stop diarrhea.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water



or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.

- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- 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 quizartinib. 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 quizartinib 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
- Headache that does not go away
- Feeling dizzy or lightheaded
- Fainting
- Weakness that interferes with your daily activities
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Wheezing, trouble breathing and/or fast breathing
- Coughing up yellow, green, or bloody mucus
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain in your abdomen that does not go away
- Signs of possible 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
- Swelling of the hands, feet, or any other part of the body
- Unexplained muscle pain, tenderness, or weakness



- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 7 months after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 month after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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