

Nilotinib tartrate (Danziten)

About This Medicine

NILOTINIB tartrate (nil OT i nib) treats leukemia. 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

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Fever
- Night sweats
- Tiredness
- Pain in the joints
- Headache
- Inflammation of the nasal passages and throat
- Cough
- Rash
- Itching

Note: Each of the side effects above was reported in 20% or greater of people treated with nilotinib tartrate. 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 bone marrow suppression
- Blood clots and events such as stroke and heart attack. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.

- Abnormal heartbeat and/or electrocardiogram (EKG/ECG), which can be life-threatening.
- Abnormal bleeding which can be life-threatening – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Swelling of the hands, feet, or any other part of the body. Fluid may build-up around your lungs and/or heart.
- Inflammation (swelling) of your pancreas
- Changes in your liver function
- Electrolyte changes
- Tumor lysis syndrome: this medicine may act on the cancer cells very quickly. This may affect how your kidneys work.
- There is a very rare increased risk of sudden death.

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

- Do not change your dose or stop taking nilotinib tartrate without first talking with your care team.
- Do not substitute nilotinib tartrate for other nilotinib products.

How to Take Your Medicine

- Take this medicine whole by mouth with water. You can take it with or without food. Do not cut, crush, or chew tablets.
- If you are unable to swallow the tablets whole, you may disperse the tablets small amount of liquid. Put tablet(s) in a small cup, add 1 to 2 teaspoons of room temperature liquid (water, milk, apple juice, pineapple juice, or cranberry juice) just enough to cover the tablet(s). After about 1 minute, swirl the mixture until the tablets are fully dispersed and take the entire mixture right away (within 15 minutes). Do not store the mixture for future use.
- **Missed dose:** If you miss a dose, take your next dose at the regular time and contact your care team. Do not take 2 doses at the same time and do not double up on the next 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.
- 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. 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

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- 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 help 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.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- 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).
- 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 are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- 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 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.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of nilotinib tartrate in your body which could make side effects worse.
- Check with your care team 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 nilotinib tartrate. Also, check with your care team 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 nilotinib tartrate as this may lower the levels of the medicine in your body, which can make it less effective.



- Medicines that treat heartburn and stomach upset may lower the effect of your cancer treatment if taken with nilotinib tartrate. Ask your care team what medicine you may take with nilotinib tartrate to help with heartburn or stomach upset.

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
- Feeling dizzy or lightheaded
- Headache that does not go away
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Wheezing and/or trouble breathing
- Cough that is bothersome
- Pain in your chest, especially when you lean forward or take deep breaths
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- 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
- No bowel movement in 3 days or when you feel uncomfortable
- Severe pain in your abdomen that may spread to your back
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Pain that does not go away, or is not relieved by prescribed medicines
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures.
- 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
- Your leg is swollen, red, warm, and/or painful
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body.
- A new rash or a rash that is not relieved by prescribed medicines



- Itching that is bothersome

Reproduction Warnings

- **Pregnancy warning:** This medicine may cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 14 days after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 14 days after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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