

Nilotinib (Tasigna)

About This Medicine

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

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
- Joint pain
- 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 patients treated with nilotinib. 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 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 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 medical team.

Important Information

- Do not change your dose or stop taking nilotinib without first talking with your doctor.

How to Take Your Medicine

- Take this medicine by mouth without food. Avoid food for at least 2 hours before the dose is taken and avoid food for at least 1 hour after the dose is taken.
- Swallow the medicine whole with water.
- If you have swallowing difficulties, you may open the capsule and sprinkle onto 1 teaspoon of applesauce and swallow immediately (within 15 minutes). Only applesauce should be used. Do not sprinkle your medicine on any other food; do not use more than 1 teaspoon of applesauce. Do not store for future use.
- **Missed dose:** If you miss a dose, take your next dose at the regular time and contact your doctor. Do not take 2 doses at the same time and do not double up on the next 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.
- 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.
- **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

- 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 doctor or nurse 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 nurse 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 doctor or nurse 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 doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your doctor or nurse 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 nurse or doctor 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 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.
- 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 in your body which could make side effects worse.
- Nilotinib capsules contain lactose. Check with your doctor if you have severe problems with lactose intolerance.
- 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 nilotinib. 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 nilotinib 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. Ask your doctor what medicine you may take with nilotinib to help with heartburn or stomach upset.

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
- 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
- Chest pain, 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
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This medicine may have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 14 days after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 14 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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