Nilotinib (Tasigna®)

Pronounced: nye-LOE-ti-nib

Classification: Tyrosine Kinase Inhibitor

About Nilotinib (Tasigna®)

Nilotinib is a type of medication called a tyrosine kinase inhibitor. A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells.

How to Take Nilotinib

Nilotinib comes as a capsule to take by mouth, twice a day. The dose should be taken on an empty stomach, either 1 hour before or 2 hours after food, with a full glass of water. The doses should be taken 12 hours apart. Swallow the tablets whole; do not crush, chew or break. If you miss a dose, take the next scheduled dose at its regular time. Do not take two doses at the same time. If you cannot swallow the capsules, you can mix the contents of the capsule with one teaspoon of applesauce and swallow the mixture immediately.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, verapamil, ketoconazole, rifampin, phenytoin, St. John’s wort, and modafinil. Be sure to tell your healthcare provider about all medications and supplements you take.

You should not take nilotinib at the same time as "heartburn" medications (including proton pump inhibitors such as prilosec, nexium, protonix; H2 blockers, such as tagamet, zantac; as these affect how nilotinib is absorbed. If needed, take these medications 10 hours before or 2 hours after nilotinib.

If you need to take an antacid that contains aluminum hydroxide, magnesium hydroxide, or simethicone, take them 2 hours before or 2 hours after nilotinib.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Nilotinib is available through retail or mail order pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network, retail or mail order pharmacy for medication distribution.
Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Nilotinib

There are a number of things you can do to manage the side effects of nilotinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Heart Rhythm Changes

Nilotinib can cause changes in the QT interval, a measure of part of the heart rhythm, which is read with an ECG (electrocardiogram). Elongation of the QT interval can result in an abnormal heart rhythm and, in some cases, can lead to death. Your healthcare team will perform an ECG to check for this abnormality prior to starting nilotinib, 7 days after starting, with any dose changes and periodically while on the drug. Abnormal blood levels of potassium and magnesium can make you more susceptible to this problem, so those blood levels will be monitored as well. Taking this medication with some other medications can worsen QT prolongation. It is important to tell your providers about all medications you are taking. If you develop an irregular heartbeat, feel your heart beating more than normal or experience fainting, notify your care provider immediately.

Nausea and/or Vomiting

Talk to your doctor or nurse so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try antacids, (e.g. milk of magnesia, calcium tablets such as Tums), saltines, or ginger ale to lessen symptoms.

Call your doctor or nurse if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Diarrhea

Diarrhea can be a serious side effect that can lead to dehydration. Notify your care team if you develop diarrhea.

Your oncology team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.

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- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the **red cell count is low**, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the **count is low** you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

In rare cases, this medication can lead to hemorrhage which is a serious bleeding issue that needs emergent treatment. If you start bleeding and it does not stop, call your provider or go to the closest emergency room.

**Muscle or Joint Pain/Aches and Headache**

Your healthcare provider can recommend medications and other strategies to help relieve pain.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Rash**

Some patients may develop a rash, very dry or itchy skin. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your doctor or nurse can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your healthcare provider of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

**Fatigue**

**Fatigue** is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Less common but important side effects can include:**

- **Liver Toxicity:** This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen, as these can be signs of liver toxicity.
- **Fluid Retention:** Nilotinib has been reported to cause fluid retention. This may result in generalized swelling, bloating of the abdomen (ascites), fluid development in the lungs (pleural effusion), or heart failure. Notify your healthcare team if you
develop swelling, shortness of breath or difficulty breathing, or if you develop a dry cough.

- **Pancreatitis:** Nilotinib can cause an inflammation of the pancreas, called pancreatitis. Contact your healthcare team if you experience sudden pain in your stomach area with nausea and vomiting.

- **Blood Clots, Heart Attack and Stroke:** Nilotinib can increase the risk of blood clots, stroke and heart attack. If you experience symptoms of these problems, you should contact your healthcare provider immediately or go to an emergency room. Symptoms can include: swelling, redness or pain in an extremity, chest pain or pressure, pain in your arm, back, neck or jaw, shortness of breath, numbness or weakness on one side of the body, trouble talking, confusion or mental status changes.

- **Tumor Lysis:** If there are a large amount of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

- **Electrolyte Abnormalities:** This medication can affect the normal levels of electrolytes (phosphate, potassium, calcium, sodium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

- **Issues with Growth in Children:** In rare cases this medication can stunt a child’s growth. This means they may have slower than normal growth during treatment with this medication. Their providers will monitor growth during and after treatment.

### Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for 2 weeks after treatment has ended. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication or for 2 weeks after your last dose.