

Nilotinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Nilotinib (ny-LOH-tih-nib): Danziten, (DAN-zi-ten), Tasigna (tuh-SIG-nuh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Danziten: Tablets taken by mouth. Tasigna and generic product: Capsules taken by mouth.

Treatment Administration and Schedule

Your nilotinib dosing instructions:

- Nilotinib comes in 2 tablet strengths (71 mg and 95 mg) and 3 capsule strengths (50 mg, 150 mg, and 200 mg).
- Do not switch between nilotinib tablets and nilotinib capsules without talking to your care team. The tablets and capsules have different amounts of the medicine.
- Your care team will tell you how many nilotinib tablets or capsules to take and when to take them.
- Take nilotinib 2 times a day, about 12 hours apart.
- Do not change your dose or stop taking nilotinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking nilotinib if you develop certain side effects.

Treatment Administration and Schedule (Continued)

- Nilotinib tablets
 - Take nilotinib tablets with or without food.
 - Swallow nilotinib tablets whole with water. Do not cut, crush, or chew the tablets.
 - If you cannot swallow nilotinib tablets whole, place tablets in a small cup, add 5 to 10 mL of room temperature liquid (such as water, milk, apple juice, pineapple juice, or cranberry juice) or just enough liquid to cover the tablets. After approximately 1 minute, when the medication is fully dispersed, swirl the solution and administer within 15 minutes. Do not store for future use.
- Nilotinib capsules
 - Take nilotinib capsules on an empty stomach.
 - Avoid eating food for at least 2 hours before the dose is taken.
 - Avoid eating food for at least 1 hour after the dose is taken.
 - Swallow nilotinib capsules whole with water. If you cannot swallow nilotinib capsules whole, tell your care team.
 - If you cannot swallow nilotinib capsules whole, you may open the nilotinib capsule and sprinkle the contents of each capsule into 1 teaspoon of applesauce. Swallow the mixture right away (within 15 minutes).
- If you miss a dose or vomit after taking a dose of nilotinib, take your next dose at your regular time. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much nilotinib, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Nilotinib

- Store nilotinib at room temperature between 68°F and 77°F (20°C and 25°C).
- People who are or may become pregnant should wear gloves when handling nilotinib.
- Keep nilotinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused nilotinib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<p>Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection</p>	<p>Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
<p>Low Platelet Count (Thrombocytopenia)</p>	<p>Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)</p>	<p>Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

<p>Fatigue</p>	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness
<p>High Blood Sugar (Hyperglycemia)</p>	<p>Description: Treatment may cause high blood sugar. Your care team will do blood tests to check you for these changes and will treat you if needed.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat a well-balanced diet. • Limit sugary drinks and foods. • Eat smaller, more frequent meals. • Be physically active for at least 30 minutes most days. • Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar

<p>High Cholesterol Levels (Hypercholesterolemia)</p>	<p>Description: Treatment can raise the cholesterol levels in your blood. While cholesterol is needed by the body, high levels can be harmful and may lead to heart issues.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Adopt a diet low in saturated and trans fats, increase fiber intake, and engage in regular physical activity. • Maintain a healthy weight. • Get regular cholesterol tests and inform the care team of any significant changes. • Do not smoke and limit alcohol consumption. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Symptoms of heart attack or stroke, such as sudden numbness, weakness, or chest pain
<p>Cough</p>	<p>Description: A cough is a reflex action that forcefully expels air from the lungs to clear the airways of irritants or mucus.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Tell your care team what your cough feels like and when it happens. • Use a humidifier and drink plenty of water. • Keep your house clean by dusting and vacuuming regularly • Avoid exposure to smoke or strong chemicals. • Your care team may recommend medicine for cough. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Trouble breathing • Chest pain or tightness • Coughing up blood
<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting

<p>Diarrhea</p>	<p>Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea
<p>Constipation</p>	<p>Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Track how often you have bowel movements each day. • Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise. • Stay active and exercise regularly. • Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise. • Your care team may recommend laxatives such as polyethylene glycol (Miralax) or senna. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative
<p>Liver Problems</p>	<p>Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal

<p>High Amylase and Levels in Your Blood</p>	<p>Description: Treatment may cause high levels of amylase in your blood. This may indicate a problem with your pancreas. Your care team will do blood tests to check you for these changes and will treat you if needed.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4°F (38°C) or higher • Fast heartbeat • Severe stomach-area (abdominal) pain that radiates to the back • Worsening pain after eating • Severe nausea or vomiting • Diarrhea • Yellowing of your skin or the white part of your eyes (jaundice)
<p>Rash or Itchy Skin</p>	<p>Description: Rash or itchy skin can cause redness, swelling, and a variety of bumps or patches (small red spots, welts, blisters, or scaly dry areas).</p> <div style="display: flex; justify-content: space-between;"> <ul style="list-style-type: none"> • Keep your skin moisturized with creams or lotions to reduce rash and itchiness. • Wear loose-fitting clothing. • Avoid perfumes and colognes, as they may worsen rash symptoms. • Limit time spent in the heat to prevent worsening symptoms. • Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn. • Wear long-sleeved clothing with ultraviolet (UV) protection and broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with sun protective factor (SPF) 30 or higher as directed. • Use lip balm with SPF 30 or higher. • Avoid tanning beds. • Your care team may recommend medicines for symptoms. <div style="width: 45%;"> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Rash or itching that continues to worsen </div> </div>

<p>Muscle or Joint Pain</p>	<p>Description: Muscle pain is soreness, aching, cramps, stiffness, tenderness, or weakness in one or more muscles. Joint pain is pain, stiffness, swelling, or reduced movement where two bones meet.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a pain diary: note pain levels, locations, and activities that make it better or worse. • Do gentle exercise (walking, stretching, yoga) to maintain mobility and strength. Check with your care team before starting a new activity. • Use a warm compress for stiff muscles or a cold pack to reduce swelling and numb pain—use what helps the area. • Your care team may recommend or prescribe medicines, including over-the-counter pain relievers. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Pain you cannot control with usual measures • Swelling, redness, or warmth in a joint • New weakness • Trouble walking or moving
<p>Headache</p>	<p>Description: Headaches are pain in your head that can vary in intensity, frequency, and location.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches. • Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches. • Apply a cold or warm compress to your forehead or neck to help ease headache pain. • Get adequate sleep (7 to 8 hours per night) and establish a regular sleep schedule. • Limit caffeine intake. • Your care team may recommend medicine for headaches. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Severe headache • More frequent or worsening headaches • Dizziness or feeling faint • Confusion • Changes in vision

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<p>Changes in the Electrical Activity of Your Heart Called QT Prolongation (Boxed Warning)</p>	<p>QT prolongation can cause irregular heartbeats that can be life-threatening. Your care team should check the electrical activity of your heart with a test called an electrocardiogram (ECG) before starting treatment and during treatment with nilotinib.</p> <ul style="list-style-type: none"> • Feel faint, lightheaded, dizzy • Fast or irregular heartbeat
<p>Decreased Blood Flow to Your Legs, Heart, or Brain</p>	<p>People who have recently been diagnosed with Ph+ CML and take nilotinib may develop decreased blood flow to the legs, heart, or brain.</p> <p>Get medical help right away if you suddenly develop any of the following symptoms:</p> <ul style="list-style-type: none"> • Chest pain or discomfort • Numbness or weakness • Problems walking or speaking • Leg pain • Your leg feels cold • Change in the skin color of your leg
<p>Swelling (Edema)</p>	<ul style="list-style-type: none"> • Swelling in your face, arms, legs, ankles, or feet • Weight gain from swelling
<p>Changes in Electrolytes</p>	<p>Treatment may cause low levels of phosphate, calcium, and sodium, and low or high levels of potassium, in your blood. Your care team will do blood tests to check you for these changes and will treat you if needed.</p> <ul style="list-style-type: none"> • New or worsening muscle weakness, cramps, or numbness • Tingling or numbness around the mouth, hands, or feet • Fast, slow, irregular, or pounding heartbeats • Severe dizziness, fainting, or near-fainting • Shortness of breath or chest pain • Severe constipation or stomach-area (abdominal) pain • Sudden weight gain • Swelling of your arms, hands, legs, or ankles
<p>Tumor Lysis Syndrome (TLS)</p>	<p>Tumor lysis happens when cancer cells break apart and flood your bloodstream with chemicals and toxins faster than your body can get rid of them. TLS is a group of conditions that affect your heart, kidneys, and muscles.</p> <ul style="list-style-type: none"> • Severe nausea, vomiting, or diarrhea • Urinating smaller amounts or having dark-colored urine • Muscle cramps or twitching • Rapid heartbeats or chest pain • Confusion or weakness • Seizures

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment can affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment and for 14 days after your last dose of nilotinib
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
- **Do NOT breastfeed** during treatment and for 14 days after your last dose of nilotinib.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- If you need to take **antacids** (medicines to treat heartburn), **do not take them at the same time that you take nilotinib**. If you take:
 - A medicine to block the amount of acid produced in the stomach (H2 blocker): Take these medicines about 10 hours before you take nilotinib, or about 2 hours after you take nilotinib.
 - An antacid that contains aluminum hydroxide, magnesium hydroxide, and simethicone to reduce the amount of acid in the stomach: Take these medicines about 2 hours before or about 2 hours after you take nilotinib.
- **Avoid grapefruit, grapefruit juice, and any supplement containing grapefruit extract** during treatment with nilotinib. Food and grapefruit products increase the amount of nilotinib in your body.
- **Abnormal growth or development in children.** Effects on growth and development have happened in children during treatment with nilotinib. Some children and adolescents may have slower-than-normal growth during treatment with nilotinib.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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