

ORAL CANCER TREATMENT EDUCATION



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NILOTINIB

Name of your medication

Generic name — nilotinib (ny-LOH-tih-nib)
Brand name — Tasigna® (tuh-SIG-nuh)

Common uses

Nilotinib is used to treat adult and pediatric patients greater than or equal to 1 year of age with chronic myeloid leukemia (CML) that is Philadelphia chromosome–positive (Ph+).

Nilotinib may also be used for other treatments.

Dose and schedule

Taking nilotinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual adult dose of nilotinib is 300 milligrams (300 mg) to 400 milligrams (400 mg) to be taken by mouth at a scheduled time twice daily. The pediatric dose is based on many factors, including height and weight, overall health, and diagnosis.
- Nilotinib should be taken on an empty stomach (at least one hour before or two hours after a meal or snack), but at the same time each day.
- Nilotinib should be taken whole and not crushed, cut, opened, or dissolved. If you are unable to swallow nilotinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of nilotinib, **do not** take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time.
- Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Storage and handling

Handle nilotinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store nilotinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep nilotinib out of reach of children and pets.
- Leave nilotinib in the provided packaging until it is ready to be taken.
- Whenever possible, give nilotinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give nilotinib to you, they may also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the nilotinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.

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5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder is used, a separate one should be used for nilotinib. **Do not** mix other medications into the box with nilotinib. The person filling the box or reminder should wear gloves. (Gloves are not necessary if you are filling the box or reminder.) When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
 - If you have any unused nilotinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of nilotinib.
 - If you are traveling, put your nilotinib in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Handling body fluids and waste

Since nilotinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take nilotinib, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or nilotinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Drug and food interactions

- Nilotinib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Nilotinib should be taken on an empty stomach (at least one hour before or two hours after a meal or snack).
- Grapefruit or grapefruit juice may interact with nilotinib; avoid eating or drinking these during your treatment with nilotinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

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- Nilotinib contains lactose in the capsules. It is not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency with a severe degree of intolerance to lactose-containing products, or glucose-galactose malabsorption. Tell your healthcare provider if you are lactose intolerant.

Side Effects of Nilotinib

The common side effects that have been known to happen in more than 30% of patients taking nilotinib are listed in the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Rash or itchy skin	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs between 10 am–4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. • Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>

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Possible Side Effect	Management
Headache	<p>Ask your provider what you may use to help with this discomfort.</p> <p>Contact your care provider right away if your headache:</p> <ul style="list-style-type: none"> • Follows a head injury • Is severe, or starts suddenly • Does not go away after 3 days • Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, made worse by coughing or lowering the head, rash, weakness in an arm or leg, or numbness
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. <ul style="list-style-type: none"> <input type="checkbox"/> Plan your activities, and do them at a time of day when you feel a bit more energetic. <input type="checkbox"/> Avoid operating heavy machinery if you feel too tired.
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid per day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • Avoid high fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
Constipation	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid per day unless your care provider has instructed you to limit your fluid intake. • Stay active and exercise, if possible. • Eat foods high in fiber like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in 3 or more days. Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener such as docusate (Colace®) and/or laxative such as senna (Senakot®) may be helpful. If these do not help within 48 hours, tell your provider.</p>

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Possible Side Effect	Management
<p>Cough or shortness of breath</p>	<p>A cough that does not produce any mucus or congestion relief (dry cough) may occur while taking this medication. If you experience any breathing problems or shortness of breath, notify your care provider immediately. This may be a serious side effect of the medication.</p>
<p>Muscle or joint pain or weakness</p>	<ul style="list-style-type: none"> • Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. • Stay as active as possible, but know that it is okay to rest as needed, too. • Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently, and do not pick your nose. • Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or hold your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

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Possible Side Effect	Management
Decreased white blood cells (WBCs) and increased risk for infection	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none">• Wash your hands often, especially before eating and after using the bathroom.• Avoid crowds and people with fevers, flu, or other infection.• Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none">• Fever (temperature more than 100.4°F or 38°C)• Chills• Sore throat• Burning with urination• Unusual tiredness• A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

Serious side effects of nilotinib

- ❑ Nilotinib may cause myelosuppression, which is a condition where you have fewer red blood cells, white blood cells, or platelets than normal. You will have regular blood tests to monitor your blood cell counts. Talk to your care team before any scheduled procedures while on nilotinib.
- ❑ Nilotinib may cause a condition called QT or QTc prolongation, which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life threatening. Tell your care team right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast, while taking nilotinib.
- ❑ Nilotinib may cause narrowing of arteries in your heart. Contact your care team if you have shortness of breath or chest pain.
- ❑ Nilotinib may be harmful to your pancreas. Seek medical attention if you have severe stomach pain or tenderness, fever, or vomiting.
- ❑ Nilotinib may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.
- ❑ Some patients taking nilotinib have experienced tumor lysis syndrome (TLS) when starting treatment. TLS is a condition that occurs when many cancer cells die very quickly and release their contents into the blood which can damage the kidneys and other parts of the body. Your care provider may give you a medication or do blood tests to check for this side effect.
- ❑ You may be at a higher risk of bleeding while taking nilotinib. Contact your care team if you notice frequent nose bleeds, blood in your stool, bleeding that occurs by itself without injury, or bleeding that will not stop after five minutes of pressure.

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- Nilotinib may cause your body to trap fluid in your body's tissues also known as edema. Let your care team know if you notice swelling in your hands, feet, or legs.
- Nilotinib can cause growth to be slowed in children and young adults. Your care provider will monitor for these effects.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

_____ (INSTITUTIONAL CONTACT INFO)

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking nilotinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 14 days after the last dose of nilotinib.
- Do not breastfeed while taking nilotinib and for 14 days after the last dose of nilotinib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on nilotinib, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about the process for obtaining your nilotinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.us.tasigna.com

Product prescribing information: www.novartis.us/sites/www.novartis.us/files/tasigna.pdf

Product resources: www.us.tasigna.com/patient-support2/download-helpful-materials;
<https://www.us.tasigna.com/patient-support/cost-copay-card>

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Additional instructions

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Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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