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2. Nilotinib

Nilotinib

Generic name: nilotinib [*nye-LOE-ti-nib*]**Brand names:** [Tasigna](#), [Danziten](#)**Dosage form:** oral capsule (150 mg; 200 mg; 50 mg)**Drug class:** [BCR-ABL tyrosine kinase inhibitors](#)[Medically reviewed](#) by Drugs.com on Mar 17, 2025. Written by [Cerner Multum](#).[Uses](#) [Side effects](#) [Warnings](#) [Before taking](#) [Dosage](#) [Interactions](#) [FAQ](#)

What is nilotinib?

Nilotinib is used to treat a type of blood cancer called Philadelphia chromosome positive [chronic myeloid leukemia](#) (CML) in adults and children who are at least 1 year old.

Nilotinib is usually given after other treatments have failed.

Nilotinib may also be used for purposes not listed in this medication guide.

Nilotinib side effects

Get emergency medical help if you have **signs of an allergic reaction**: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Contact your doctor right away or get emergency medical help if you have symptoms of a serious heart problem: fast or pounding heartbeats and sudden dizziness (like you might pass out).

Nilotinib may cause serious side effects. Call your doctor at once if you have:

- unusual bleeding (bruises, blood in your urine or stools);
- swelling, rapid weight gain, feeling short of breath;
- **bleeding in the brain**--sudden headache, confusion, vision problems, and dizziness;
- **signs of liver or pancreas problems**--upper stomach pain (that may spread to your back), nausea or vomiting, dark urine, jaundice (yellowing of the skin or eyes);
- **low blood cell counts**--fever, chills, night sweats, mouth sores, pale skin, unusual weakness;
- **signs of decreased blood flow**--leg pain or cold feeling, chest pain, numbness, trouble walking, speech problems; or
- **signs of tumor cell breakdown**--confusion, weakness, muscle cramps, nausea, vomiting, fast or [slow heart rate](#),

decreased urination, tingling in your hands and feet or around your mouth.

Nilotinib can affect growth in children and teenagers. Tell your doctor if your child is not growing at a normal rate while using nilotinib.

Common side effects of nilotinib may include:

- nausea, vomiting, diarrhea, [constipation](#);
- rash, temporary hair loss;
- night sweats;
- pain in your bones, spine, joints, or muscles;
- headache, feeling tired; or
- runny or stuffy nose, sneezing, cough, [sore throat](#).

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Nilotinib side effects](#) (more detail)

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Warnings

You should not use nilotinib if you have [long QT syndrome](#), or low blood levels of potassium or magnesium.

Nilotinib can cause a serious heart problem, especially if you use certain other medicines at the same time. Tell your doctor about all your other medicines. Your heart function may need to be checked before and during treatment with nilotinib.

Call your doctor right away or get emergency medical help if you have fast or pounding heartbeats and sudden dizziness (like you might pass out).

Avoid eating anything for at least 2 hours before and 1 hour after you take nilotinib.

Before taking this medicine

You should not use nilotinib if you are allergic to it, or if you have:

- low blood levels of potassium or magnesium; or
- a heart rhythm disorder called long QT syndrome.

Tell your doctor if you have ever had:

- [heart disease](#), heartbeat problems, or long QT syndrome (in you or a family member);
- a stroke;
- blood circulation problems in your legs;
- bleeding problems;
- low blood levels of potassium or magnesium;
- severe problems with lactose (milk sugar);
- [liver disease](#);
- [pancreatitis](#); or
- surgical removal of your stomach (total gastrectomy).

You may need to have a negative pregnancy test before starting this treatment.

Do not use nilotinib if you are pregnant. It could harm the unborn baby. Use effective [birth control](#) to prevent pregnancy while you are using nilotinib and for at least 14 days after your last dose.

Do not breastfeed while you are taking nilotinib and for at least 14 days after your last dose.

How should I take nilotinib?

Nilotinib is usually taken every 12 hours. Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Take nilotinib on an empty stomach. **Do not take with food.** Food can increase your blood levels of nilotinib and may increase harmful side effects.

Avoid eating anything for at least 2 hours before and 1 hour after you take nilotinib.

Take this medicine with a full glass of water. **Swallow the capsule whole.**

If you cannot swallow a capsule whole, open it and sprinkle the medicine into a teaspoon of applesauce. Swallow the mixture right away without chewing. Do not save it for later use.

Nilotinib is to be taken long-term. **You should not stop using nilotinib unless your doctor tells you to.**

Nilotinib can lower your blood cell counts. **Your blood will need to be tested often.** Your cancer treatments may be delayed based on the results.

Nilotinib can cause a serious heart problem. Your heart function may be checked with an electrocardiograph or ECG (sometimes called an EKG) before and during your treatment with nilotinib.

Store at room temperature away from moisture and heat.

Nilotinib dosing information

Usual Adult Dose for Chronic Myelogenous Leukemia:

Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP): 300 mg orally twice a day

Resistant or intolerant Ph+ CML-CP and chronic myeloid leukemia in accelerated phase (CML-AP): 400 mg orally twice a day

Comments:

-Doses should be administered about 12 hours apart.

-This drug may be given in combination with hematopoietic growth factors (e.g., erythropoietin, granulocyte colony-stimulating factor [G-CSF]), [hydroxyurea](#), or [anagrelide](#) if clinically indicated.

Uses:

-For the treatment of patients with newly diagnosed Ph+ CML-CP

-For the treatment of patients with chronic phase and accelerated phase Philadelphia chromosome positive [chronic myelogenous leukemia](#) (Ph+ CML) resistant/intolerant to prior therapy that included imatinib

Usual Pediatric Dose for Chronic Myelogenous Leukemia:

1 year or older: 230 mg/m² orally twice a day

-Rounded to the nearest 50 mg dose

-Maximum dose: 400 mg/dose

Dosing based on BSA:

-BSA up to 0.32 m²: 50 mg orally twice a day

-BSA 0.33 to 0.54 m²: 100 mg orally twice a day

- BSA 0.55 to 0.76 m²: 150 mg orally twice a day
- BSA 0.77 to 0.97 m²: 200 mg orally twice a day
- BSA 0.98 to 1.19 m²: 250 mg orally twice a day
- BSA 1.2 to 1.41 m²: 300 mg orally twice a day
- BSA 1.42 to 1.63 m²: 350 mg orally twice a day
- BSA at least 1.64 m²: 400 mg orally twice a day

Comments:

- Doses should be administered about 12 hours apart.
- Therapy should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs.
- This drug may be given in combination with hematopoietic growth factors (e.g., erythropoietin, G-CSF), hydroxyurea, or anagrelide if clinically indicated.

Uses:

- For the treatment of patients with newly diagnosed Ph⁺ CML-CP
- For the treatment of patients with chronic phase and accelerated phase Ph⁺ CML with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

 [Detailed Nilotinib dosage information](#)

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. **Do not** take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose symptoms may include [drowsiness](#) and vomiting.

What should I avoid while taking nilotinib?

Grapefruit may interact with nilotinib and lead to unwanted side effects. **Avoid the use of grapefruit products.**

Avoid taking a stomach acid reducer (such as Pepcid, Tagamet, or Zantac) within **10 hours before** or **2 hours after** you take nilotinib.

Avoid taking an antacid that contains aluminum, magnesium, or [simethicone](#) (such as Di-Gel, Gaviscon, Maalox, [Milk of Magnesia](#), Mylanta, or Rolaids) within **2 hours before** or **2 hours after** you take nilotinib.

What other drugs will affect nilotinib?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Nilotinib can cause a serious heart problem. Your risk may be higher if you also use certain other medicines for infections, asthma, heart problems, [high blood pressure](#), [depression](#), mental illness, cancer, malaria, or HIV.

Many drugs can affect nilotinib. This includes prescription and over-the-counter medicines, vitamins, and [herbal products](#). **Not all possible interactions are listed here.** Tell your doctor about all your current medicines and any medicine you start or stop using.

 [Nilotinib drug interactions](#) (more detail)

Does nilotinib interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

+

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Tasigna, Danziten

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Other brands

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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability	
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Pregnancy & Lactation	
	Risk data available
CSA Schedule*	
N/A	Not a controlled drug
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