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2. Tasigna

Generic name: nilotinib [*nye-LOE-ti-nib*] **Drug class:** BCR-ABL tyrosine kinase inhibitors

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What is Tasigna?

Tasigna is a cancer medicine that interferes with the growth and spread of cancer cells in the body.

Tasigna 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.

Tasigna is usually given after other medications have been tried without success.

Warnings

You should not use Tasigna if you have long QT syndrome, or low blood levels of potassium or magnesium.

Tasigna 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 this medicine.

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).

Take Tasigna on an empty stomach. Avoid eating anything for at least 2 hours before and 1 hour after you take your dose.

Before taking this medicine

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

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

To make sure Tasigna is safe for you, 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 Tasigna if you are pregnant. It could harm the unborn baby. Use effective birth control to prevent pregnancy while you are using this medicine and for at least 14 days after your last dose.

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

Tasigna pregnancy and breastfeeding warnings (more detail)

How should I take Tasigna?

Tasigna is usually taken every 12 hours. Follow the directions on your prescription label. Do not take this medicine in larger or smaller amounts or for longer than recommended.

Take Tasigna 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 Tasigna.

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

If you cannot swallow a capsule whole you may open the capsule and sprinkle the medicine into no more than 1 teaspoon of applesauce. Swallow right away without chewing. Do not save the mixture for later use.

Tasigna is to be taken long-term. You should not stop using this medicine unless your doctor tells you to.

Tasigna can lower blood cells that help your body fight infections. Your blood will need to be tested often. Your cancer treatments may be delayed based on the results of these tests.

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 this medicine.

Store at room temperature away from moisture and heat.

Read all patient information, medication guides, and instruction sheets provided to you. Ask your doctor or pharmacist if you have any questions.

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 Tasigna dosage information

What happens if I miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

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 to avoid

Grapefruit and grapefruit juice may interact with nilotinib and lead to unwanted side effects. Avoid the use of grapefruit products while taking Tasigna.

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

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 Tasigna.

Nilotinib can pass into body fluids (urine, feces, vomit). Caregivers should wear rubber gloves while cleaning up a patient's body fluids, handling contaminated trash or laundry or changing diapers. Wash hands before and after removing gloves. Wash soiled clothing and linens separately from other laundry.

Tasigna side effects

Get emergency medical help if you have **signs of an allergic reaction to Tasigna**: 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).

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 this medicine.

Common Tasigna side effects 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.

1 Tasigna side effects (more detail)

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What other drugs will affect Tasigna?

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.

Tasigna 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 interact with 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.

1 Tasigna drug interactions (more detail)

Does Tasigna interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Tasigna	
+	
Enter a drug name	Add

Popular FAQ

Gleevec vs Sprycel vs Tasigna - how do they compare?	~
What happens if you take Tasigna with food?	~
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More FAQ

• Does Tasigna (nilotinib) cause hair loss?

References

1. Tasigna Product Label

More about Tasigna (nilotinib)

- · Check interactions
- · Compare alternatives
- Pricing & coupons
- Reviews (30)
- Drug images
- Side effects
- Dosage information
- During pregnancy
- FDA approval history
- Drug class: BCR-ABL tyrosine kinase inhibitors

- Breastfeeding
- En español

Patient resources

Other brands

Danziten

Professional resources

- Tasigna prescribing information
- Nilotinib (AHFS Monograph)

Other brands

Danziten

Related treatment guides

• Chronic Myelogenous Leukemia

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Tasigna 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

Rx Prescription only

Pregnancy & Lactation

ഏ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2007

User Reviews & Ratings

Images

Tasigna 200 mg (NVR TKI)



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