

Medication Guide
TASIGNA® (ta-sig-na)
(nilotinib)
capsules

What is the most important information I should know about Tasigna?

Tasigna can cause a possible life-threatening heart problem called QTc prolongation. QTc prolongation causes an irregular heartbeat, which may lead to sudden death.

Your healthcare provider should check the electrical activity of your heart with a test called an electrocardiogram (ECG):

- before starting Tasigna
- 7 days after starting Tasigna
- with any dose changes
- regularly during Tasigna treatment

You may lower your chances for having QTc prolongation with Tasigna if you:

- **Take Tasigna on an empty stomach:**
 - Avoid eating food for at least 2 hours before the dose is taken, and
 - Avoid eating food for at least 1 hour after the dose is taken.
- Avoid grapefruit, grapefruit juice, and any supplement containing grapefruit extract while taking Tasigna. Food and grapefruit products increase the amount of Tasigna in your body.
- Avoid taking other medicines or supplements with Tasigna that can also cause QTc prolongation.
- Tasigna can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects.
- Do not take any other medicine while taking Tasigna unless your healthcare provider tells you it is okay to do so.
- If you cannot swallow Tasigna capsules whole, you may open the Tasigna capsule and sprinkle the contents of each capsule in 1 teaspoon of applesauce (puréed apple). Swallow the mixture right away (within 15 minutes). For more information, see “How should I take Tasigna?”

Call your healthcare provider right away if you feel lightheaded, faint, or have an irregular heartbeat while taking Tasigna. These can be symptoms of QTc prolongation.

What is Tasigna?

Tasigna is a prescription medicine used to treat a type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in adults who:

- are newly diagnosed, **or**
- are no longer benefiting from previous other treatments, including treatment with imatinib (Gleevec), **or**
- have taken other treatments, including imatinib (Gleevec), and cannot tolerate them

It is not known if Tasigna is safe and effective in children.

Who should not take Tasigna?

Do not take if you have:

- low levels of potassium or magnesium in your blood
- long QTc syndrome

What should I tell my healthcare provider before starting Tasigna?

Before taking Tasigna, tell your healthcare provider about all of your medical conditions, including if you :

- have heart problems
- have had a stroke or other problems due to decreased blood flow to the brain
- have problems with decreased blood flow to your legs
- have irregular heartbeat
- have QTc prolongation or a family history of it
- have liver problems
- have had pancreatitis
- have low blood levels of potassium or magnesium in your blood
- have a severe problem with lactose (milk sugar) or other sugars. Tasigna capsules contain lactose. Most people who have mild or moderate lactose intolerance can take Tasigna.
- have bleeding problems
- had a surgical procedure involving the removal of the entire stomach (total gastrectomy)
- are pregnant or plan to become pregnant. Tasigna may harm your unborn baby. If you are able to become pregnant,

you should use effective birth control during treatment with Tasigna. Talk to your healthcare provider about the best birth control methods to prevent pregnancy while you are taking Tasigna.

- are breastfeeding or plan to breastfeed. It is not known if Tasigna passes into your breast milk. You and your healthcare provider should decide if you will take Tasigna or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

If you need to take antacids (medicines to treat heartburn) do not take them at the same time that you take Tasigna. 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 Tasigna, **or about 2 hours after** you take Tasigna.
- **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 Tasigna.

Tasigna can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects. **See “What is the most important information I should know about Tasigna?”**

How should I take Tasigna?

- Take Tasigna exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking Tasigna unless your healthcare provider tells you.
- Tasigna is a long-term treatment.
- Your healthcare provider will tell you how many Tasigna capsules to take and when to take them.
- **Tasigna must be taken on an empty stomach.**
 - **Avoid eating food for at least 2 hours before the dose is taken, and**
 - **Avoid eating food for at least 1 hour after the dose is taken.**
- Swallow Tasigna capsules whole with water. If you cannot swallow Tasigna capsules whole, tell your healthcare provider.
- **If you cannot swallow Tasigna capsules whole:**
 - **Open the Tasigna capsules and sprinkle the contents in 1 teaspoon of applesauce (puréed apple).**
 - **Do not use more than 1 teaspoon of applesauce.**
 - **Only use applesauce. Do not sprinkle Tasigna onto other foods.**
 - **Swallow the mixture right away (within 15 minutes).**
- Do not drink grapefruit juice, eat grapefruit, or take supplements containing grapefruit extract at any time during treatment. **See “What is the most important information I should know about Tasigna?”**
- If you miss a dose, just 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 Tasigna, call your healthcare provider or poison control center right away. Symptoms may include vomiting and drowsiness. During treatment with Tasigna your healthcare provider will do tests to check for side effects and to see how well Tasigna is working for you. The tests will check your:
 - heart
 - blood cells (white blood cells, red blood cells, and platelets). Your blood cells should be checked every 2 weeks for the first 2 months and then monthly.
 - electrolytes (potassium, magnesium)
 - pancreas and liver function
 - bone marrow samples

Your healthcare provider may change your dose. Your healthcare provider may have you stop Tasigna for some time or lower your dose if you have side effects with it.

What are the possible side effects of Tasigna?

Tasigna may cause serious side effects, including:

- **See “What is the most important information I should know about Tasigna?”**
- **Decreased blood flow to the leg, heart, or brain.** People who have recently been diagnosed with Ph+ CML and take Tasigna may develop decreased blood flow to the leg, the heart, or brain.

Get medical help right away if you suddenly develop any of the following symptoms:

- 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
- **Low blood counts.** Low blood counts are common with Tasigna. Your healthcare provider will check your blood counts regularly during treatment with Tasigna. Symptoms of low blood counts include:
 - unexplained bleeding or bruising
 - blood in urine or stool
 - unexplained weakness
- **Liver problems.** Symptoms include yellow skin and eyes.
- **Pancreas inflammation (pancreatitis).** Symptoms include sudden stomach area pain with nausea and vomiting.
- **Bleeding in the brain.** Symptoms include sudden headache, changes in your eyesight, not being aware of what is going on around you and becoming unconscious.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have:
 - **kidney failure and the need for dialysis treatment**
 - **an abnormal heart beat**

Your healthcare provider may do blood tests to check you for TLS.

- **Bleeding.** Tell your healthcare provider right away if you develop any signs and symptoms of bleeding during treatment with Tasigna.
- **Fluid retention.** Your body may hold too much fluid (fluid retention). Symptoms of fluid retention include shortness of breath, rapid weight gain, and swelling.

The most common side effects of Tasigna include:

- | | |
|---|--|
| <ul style="list-style-type: none"> • low blood count • nausea • rash • headache • tiredness • itching • vomiting | <ul style="list-style-type: none"> • diarrhea • cough • constipation • muscle and joint pain • runny or stuffy nose, sneezing, sore throat • fever • night sweats |
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These are not all of the possible side effects of Tasigna.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Tasigna?

- Store Tasigna at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.

Keep Tasigna and all medicines out to the reach of children.

General information about the safe and effective use of Tasigna.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Tasigna for a condition for which it was not prescribed. Do not give Tasigna to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Tasigna that is written for health professionals.

What are the ingredients in Tasigna?

Active ingredient: nilotinib

Inactive ingredients: colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate and poloxamer 188.

The capsule shell contains gelatin, iron oxide (red), iron oxide (yellow), iron oxide (black), and titanium dioxide.

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For more information, go to www.Tasigna.com or call 1-866-411-8274.