Medication guide

TASIGNA® (ta-sig-na)
(nilotinib)
Capsules

Read this Medication Guide before you start taking Tasigna® and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

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 doctor 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. Do not take Tasigna with food.
  - at least 2 hours after eating any food, and
  - wait at least 1 hour before eating any food
- 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 doctor 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 doctor 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 or 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 doctor before starting Tasigna?

Tasigna may not be right for you. Before taking Tasigna, tell your doctor about all of your medical conditions, including if you have:
- heart problems
- irregular heartbeat
- QTc prolongation or a family history of it
- liver problems
- had pancreatitis
- low blood levels of potassium or magnesium in your blood
- a severe problem with lactose (milk sugar) or other sugars. The Tasigna capsules contain lactose. Most patients who have mild or moderate lactose intolerance can take Tasigna.
- 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 doctor 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 doctor should decide if you will take Tasigna or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non prescription medicines, vitamins and herbal supplements.

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?”

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take Tasigna?
- Take Tasigna exactly as your doctor tells you to take it. Do not change your dose or stop taking Tasigna unless your doctor tells you.
- Tasigna is a long-term treatment.
- Your doctor will tell you how many Tasigna capsules to take and when to take them.
- **Do not take Tasigna with food. Take Tasigna at least 2 hours after you eat and at least 1 hour before you eat.**
- Swallow Tasigna capsules whole with water. If you cannot swallow Tasigna capsules whole, tell your doctor

- **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 as scheduled. Do not make up for a missed dose.
- If you take too much Tasigna, call your doctor or poison control center right away. Symptoms may include vomiting and drowsiness. During treatment with Tasigna your doctor 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 two weeks for the first two months and then monthly.
    - electrolytes (potassium, magnesium)
    - pancreas and liver function
    - bone marrow samples
- Your doctor may change your dose. Your doctor 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?"
- **Low blood counts.** Low blood counts are common with Tasigna. Your doctor 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 damage.** 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 doctor may do blood tests to check you for TLS.

The most common side effects of Tasigna include:

- low blood count
- constipation

- rash
- nausea
- fever
- headache
- itching
- tiredness
- stomach (abdominal) pain
- diarrhea
- muscle and joint pain
- back pain
- muscle spasms
- weakness
- hair loss
- runny or stuffy nose, sneezing, sore throat
- cough

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of Tasigna. For more information, ask your doctor or pharmacist.

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, 59° to 86°F (15° to 30°C).
- Safely throw away medicine that is out of date or no longer needed.
- **Keep Tasigna and all medicines out of the reach of children.**

General information about 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 problem you have. It may harm them.

This Medication Guide summarizes the most important information about Tasigna. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Tasigna that is written for healthcare professionals.

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

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, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide black or iron oxide red for stamping of the imprint (E172).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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