

- Continue taking Tasigna every day for as long as their doctor tells them.
- This is a long-term treatment.
- Do not to change dose or stop taking Tasigna without first consulting their doctor.
- If a dose is missed, take the next dose as scheduled. Do not take a double dose to make up for the forgotten capsules.

17.5 Medication Guide

TASIGNA[®] (ta-sig-na)

(nilotinib)

Capsules

Read the Medication Guide that comes with Tasigna[®] before you start using it and each time you get a refill. There may be new information. This Medication Guide 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 heart beat, which may lead to sudden death.

Your doctor should check your heart with a test called an "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.** Take Tasigna:
 - 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 blood levels of Tasigna in your body.

- **avoid taking other medicines or supplements with Tasigna that can also cause QTc prolongation.**
 - Tell your doctor about all of the medicines you take including prescription medicines, over-the-counter medicines, vitamins and herbal supplements. Tasigna can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects.
 - Know the medicines you take. Keep a list of your medicines with you to show to your doctor and pharmacist. Do not take any other medicine while taking Tasigna unless your doctor tells you it is okay to do so.

Call your doctor right away if you faint or have an irregular heartbeat while taking Tasigna. These can be symptoms of QTc prolongation.

What is Tasigna?

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

- are no longer benefiting from another treatment, including treatment with imatinib (Gleevec[®])
- have taken other treatments and cannot tolerate them

Tasigna has not been studied in children.

What should I tell my doctor before starting Tasigna?

Tell your doctor about all of your health problems, including if you:

- have any heart problems
- have an irregular heart beat
- have QTc prolongation or a family history of it
- have liver problems
- have had pancreatitis
- have low blood levels of potassium or magnesium
- have a severe problem with lactose (milk sugar) or other sugars. The Tasigna capsules contain lactose.

Tell your doctor if you are pregnant or planning to become pregnant. Tasigna can harm a fetus (unborn baby).

- Women who can get pregnant must use effective birth control during treatment with Tasigna.

Tell your doctor if you are breastfeeding. Women should not breastfeed while taking Tasigna.

How should I take Tasigna?

- Take Tasigna exactly as your doctor has prescribed. Do not stop taking Tasigna or change your dose of Tasigna unless told to do so by your doctor.
- Tasigna should be taken twice a day, with about 12 hours between the two doses.
- **Do NOT take Tasigna with food. Take Tasigna at least 2 hours after any food and then wait at least 1 hour before eating again.**
- Swallow Tasigna capsules whole with water.
- Do not open Tasigna capsules.
- Do not drink grapefruit juice, eat grapefruit, or take supplements containing grapefruit extract. It may affect the levels of Tasigna in the blood.
- If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for a missed dose.
- If you take too much Tasigna, call your doctor or poison control center right away.
- Your doctor will check your heart, do regular blood tests and take bone marrow samples during treatment with Tasigna. These are done to check for side effects with Tasigna and to see how well Tasigna is working for you.
- Your doctor may have you stop Tasigna for some time or reduce your dose if you have side effects with it.

What are the possible side effects of Tasigna?

Possible Serious side effects include:

- **QTc Prolongation.** (See “what is the most important information I should know about Tasigna?”)
Symptoms can include an irregular heart beat and fainting.
- **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.
- **Fluid retention** including fluid build-up around the heart or lungs. Symptoms include:
 - shortness of breath
 - swelling of hands, ankles, feet, or face
- **Pancreas inflammation (pancreatitis).** Symptoms include sudden stomach area pain with nausea and vomiting.

Call your doctor right away if you have any of the above problems or symptoms while taking Tasigna.

The most common side effects of Tasigna include:

- low blood count
- rash
- nausea
- headache
- itching
- tiredness
- diarrhea
- constipation

How should I store Tasigna?

- Store Tasigna at room temperature, 59° to 86°F (15° to 30°C).
- Do not use Tasigna after the expiration date which is stated on the carton after EXP. The expiration date refers to the last day of that month.
- **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 highlights 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 written for healthcare professionals.
- For more information call 1-866-411-TASIGNA (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 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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