

Suspected adverse reactions and medication errors associated with the use of TASIGNA should be reported to:

Medicines Authority Post-licensing Directorate,
203, Level 3, Rue D'Argens, Gzira GZR 1368

or at:

www.medicinesauthority.gov.mt/adrportal

Alternatively at:

Novartis Pharma Services Inc. Representative Office Malta
by phone on 22983217 or 21222872

Tasigna[®]
(nilotinib)

**Important
Information About
How to Take Your
Medication**

Important Things to Know About TASIGNA

What **IS** TASIGNA?

TASIGNA is a medicine that is available by prescription only.

TASIGNA is a prescription medicine used to treat a type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in adult patients who either

- Are newly diagnosed
- Are no longer benefiting from previous other treatments, including Glivec (imatinib)
- Have taken other treatments, including imatinib, and cannot tolerate them

What does TASIGNA look like?

- **For newly diagnosed patients:** TASIGNA 150-mg capsules are red and come in a daily dosing package that has been designed to be convenient for patients. Each blister pack contains 1 day's dose; the morning and evening doses are perforated to allow separation



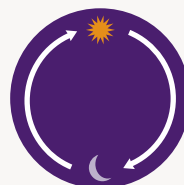
150-mg package

- **For patients who have not responded to or tolerated imatinib:** TASIGNA 200-mg capsules are pale yellow and come in a daily dosing blister pack similar to the 150-mg version



What to do

- **Take 2 capsules twice every day**, around the same time each day, as prescribed by your doctor. This is different from imatinib, which is taken once daily by most patients. Please keep this in mind
- **Swallow the capsules whole, followed by a full glass of water.** Do not chew the capsules



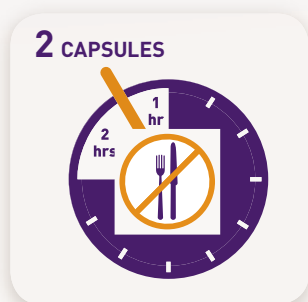
- **Take each dose about 12 hours apart.** For example, if you take the first dose at 10 AM, wait until 10 PM before you take the second dose
- **Take TASIGNA when it is first prescribed.** Whatever is left of your previous medication should be discarded

What should I do if I forget to take TASIGNA?

- If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for the forgotten capsules

What **NOT** to do

- **Do NOT take TASIGNA with food.** Taking TASIGNA with food will increase the amount of TASIGNA circulating in your blood, and can cause dangerous side effects such as QT prolongation (see page 6)



- No food should be eaten for 2 hours before and at least 1 hour after taking a dose

- **Do NOT consume grapefruit or grapefruit juice at any time during treatment with TASIGNA.**

Grapefruit interacts with an enzyme in the body that may increase the amount of TASIGNA circulating in your blood, possibly to a harmful level



- Please ask your doctor about any other foods that should be avoided with TASIGNA
- **Do NOT take any other medicines without talking to your doctor or pharmacist.** This includes over-the-counter and herbal remedies (eg, St John's wort), and medicines used to treat different infections. The doctor will decide if any changes need to be made to the medicines that you are taking

What should I do if I am sick and vomit after taking a dose of TASIGNA?

- If you are sick and experience vomiting after taking TASIGNA, you should NOT take another dose. Speak to your doctor immediately

What should I do if I take more TASIGNA than I should?

- If you have taken more TASIGNA than prescribed, or if someone else accidentally takes your medication, contact a doctor or the hospital for advice right away. Show them the pack of capsules. Medical treatment may be necessary

Tell your doctor if:

- You have QT prolongation or a family history of it
- You experience fainting or have an irregular heartbeat while taking TASIGNA
 - These can be signs of QT prolongation
- You know that you suffer from low blood levels of electrolytes, such as potassium or magnesium
- If you develop swollen ankles or shortness of breath while taking TASIGNA
- You have a heart disorder, liver disorder, high cholesterol, or diabetes or are taking medicines for these conditions
- You are pregnant, breast-feeding, or lactose intolerant

For more information, please refer to the TASIGNA Package Leaflet

REMEMBER:

- **TASIGNA can cause a possible life-threatening heart problem called QT prolongation**
 - QT prolongation can cause an irregular heartbeat and even lead to sudden death in some patients
- Your heart should be checked with a test called an “ECG” before starting treatment
- Your doctor should check the levels of electrolytes (potassium and magnesium) in your blood
- You can **lower your risk of QT prolongation** with TASIGNA. Follow these important safety rules:
 - Take TASIGNA on an empty stomach.
DO NOT TAKE TASIGNA WITH FOOD
 - Avoid grapefruit and grapefruit products
 - Avoid medicines that are strong CYP3A4 inhibitors (your doctor will determine if any of your medicines are strong CYP3A4 inhibitors)
 - Avoid other medicines or supplements that can also cause QT prolongation
- Call your doctor right away if you faint or have an irregular heartbeat while taking TASIGNA
 - These can be symptoms of QT prolongation
- TASIGNA can cause elevation of cholesterol and glucose levels in the blood
 - Your doctor should check your cholesterol and glucose levels
- Tell your doctor or pharmacist if you have any side effects during treatment with TASIGNA

Notes:

[illegible]