

# Tasigna<sup>®</sup> (nilotinib)

## Important Information About How to Take Your Medication

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

Malta Medicines Authority,  
Sir Temi Zammit Buildings,  
Malta Life Sciences Park,  
San Gwann. SGN 3000.

Or at: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

Alternatively at: Novartis Pharma Services Inc., Representative Office,  
Malta by phone on +356 21222872.



## What is Tasigna® (nilotinib) used for?

Tasigna is a prescription medicine used to treat a type of leukemia called Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in adult and pediatric 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

## The Do's and Don'ts of taking Tasigna

### What to do

- **Take the capsules twice every day**, around the same time each day, as prescribed by your doctor. This is different from Glivec, 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. If a dose is missed, patients should not make up the dose, but take the next dose as scheduled.
- Under the supervision of a doctor, in case you have achieved a long-lasting deep molecular response (e.g. at least MR4.5), you may perhaps be eligible to discontinue Tasigna. If you do discontinue Tasigna, you will need to have frequent blood and molecular testing to monitor your CML disease status, and see if you need to restart Tasigna treatment.



## What NOT to do

- **Do NOT take Tassigna with food.** Taking food with Tassigna will increase the amount of Tassigna circulating in your blood, and can cause severe side effects such as QT prolongation.
- 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 Tassigna.**
- Grapefruit interacts with an enzyme in the body that may increase the amount of Tassigna circulating in your blood, possibly to a harmful level.
- Please ask your doctor about any other foods that should be avoided with Tassigna.
- **Do NOT take any other medicines without talking to your doctor or pharmacist.** This includes over-the-counter and herbal remedies (e.g. St. John's wort). The doctor will decide if any changes need to be made to the medicines that you are taking.
- Do not stop taking Tassigna unless your doctor tells you to do so.

## What should I do if I take more Tassigna than I should?

- If you have taken more Tassigna 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.

## What to do if you feel sick

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



### **Tell your doctor if:**

- You have QT prolongation or a family history of it.
- You experience fainting or have an irregular heartbeat while taking Tassigna® (nilotinib).
  - These can be signs of QT prolongation.
- You know that you suffer from low blood levels of electrolytes, such as potassium or magnesium.
- You develop swelling of feet or hands, generalized swelling or rapid weight gain, as these may be signs of severe fluid retention. Uncommon cases of severe fluid retention have been reported.
- 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.
- You have any side effects during treatment with Tassigna.
- You develop chest pain or discomfort, numbness or weakness, problems with walking or with your speech, pain, discoloration or a cool feeling in a limb, **tell your doctor immediately**, as these may be signs of a cardiovascular event. Serious cardiovascular events, including problems with the blood flow to the leg (peripheral arterial occlusive disease), ischemic heart disease, and problems with blood supply to the brain (ischemic cerebrovascular disease) have been reported. Your doctor should assess the level of fats (lipids) and sugar in your blood before initiating treatment and during Tassigna treatment.
- If you get pain in muscles, joints, limbs or your back after Tassigna has been discontinued.

**Marketing Authorisation Holder: Novartis Europharm Limited, Frimley Business Park, Camberley, GU16 7SR, United Kingdom.**

**Local Representative: Novartis Pharma Services Inc., Representative Office Malta. Tel No.: +356 21222872.**