Tasigna® (nilotinib)

Important Information About How to Take Your Medication

NOVARTIS

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 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 2 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.

What NOT to do

- **Do NOT take Tasigna with food.** Taking food with Tasigna will increase the amount of Tasigna 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 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 (e.g. St. John's wort). The doctor will decide if any changes need to be made to the medicines that you are taking.

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.

What to do if you feel sick

- If you are sick and experience vomiting after taking Tasigna, 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 Tasigna® (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 Tasigna.
- 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 Tasigna treatment.

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.

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

MAH Address: Novartis Europharm Limited, Frimley Business Park Camberley, GU167SR, United Kingdom.