

Tasigna[®]

patient information:
a quick guide

What do I need to
know about taking

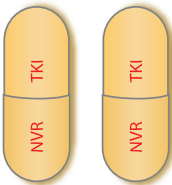


Acknowledgements

This booklet was prepared thanks to the advice of a panel of patient advocates and haematology and oncology nurses from the following countries: Czech Republic, France, Germany, Greece, Ireland, Italy, Spain, Switzerland, The Netherlands, UK.

What is Tasigna®?

Tasigna® is the brand name of a medicine called nilotinib. It comes in pale yellow capsules, each containing 200 mg of nilotinib.

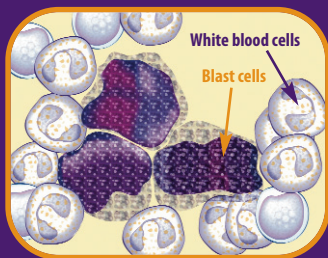


CPO to insert
local pack picture

How does Tasigna[®] work?

Tasigna[®] (nilotinib) works by blocking the incorrect message sent by the Philadelphia chromosome – in this way Tasigna[®] works very much like Glivec[®] (imatinib). This incorrect message makes the bone marrow produce too many damaged white blood cells (sometimes called ‘blasts’) – a common sign of Ph+ CML.

When you stop the bone marrow producing too many damaged white blood cells, then the production of all of the healthy blood cells can return to normal.



CPO to amend according to local information available
[More detailed information about Ph+ CML and its treatment can be found in the Tasigna booklet, in CML Alliance booklets and topic cards or in other material available in the specific country. Please contact (appropriate contact information to be supplied by each country/region) if you would like to receive these materials.]

Why do I need to take Tasigna[®]?

You have been prescribed Tasigna[®] for the treatment of the chronic or accelerated phase of Philadelphia chromosome-positive (Ph+) chronic myeloid leukaemia (CML) because you are no longer benefiting from previous treatment with Glivec[®] (also known as imatinib). This is known as becoming **'imatinib-resistant'**.

Or it may be because you experienced side effects with Glivec[®] and you are not able to continue taking it – this is known as being **'imatinib-intolerant'**.

Tasigna[®] must be used with caution in patients with cardiac (heart) or hepatic (liver) problems. You should consult your doctor about any heart or liver problem that you are aware of.

What do I need to know about taking **Tasigna®**?

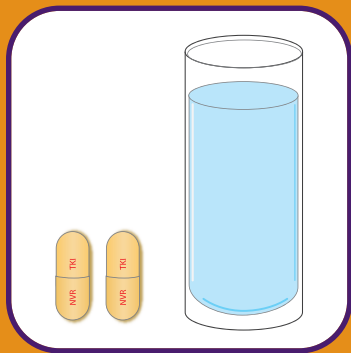
FAST FOR AT LEAST 2 HOURS BEFORE TAKING TASIGNA® AND 1 HOUR AFTER

What is the usual dose of **Tasigna®**?

Take **TWO** 200 mg capsules (pills) **TWICE EVERY DAY**. Take each dose with a **LARGE GLASS OF WATER**

(about 8 oz / 250 ml or half a pint).

Remember to **SWALLOW THE CAPSULES WHOLE** without breaking or chewing them.



When do I need to take my **Tasigna[®]** pills?

Take the doses of Tasigna[®] 12 hours apart and at the same times each day. **DO NOT TAKE WITH FOOD.**



Before taking your two capsules of Tasigna[®] wait for at least 2 hours or more after your last meal. Then do not eat again for 1 hour (or more) after taking your pills.

You may drink water whilst you are fasting before or after taking your Tasigna[®].

Why must I take Tasigna[®] while fasting?

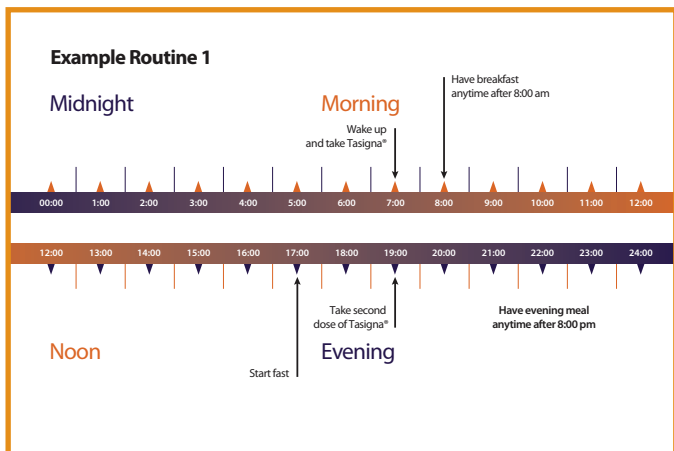
If Tasigna[®] is taken together with any food, or shortly before or after a meal, the amount of Tasigna[®] in your blood will increase. High levels of Tasigna[®] in your blood will not make it work any better. In fact, if you have too much Tasigna[®] in your blood you may experience unwanted side effects. If you experience severe side effects you may not be able to continue with further treatment.



How will my response to **Tasigna[®]** be monitored?

You will have regular tests including blood tests during treatment. These will check the number of blood cells (white blood cells, red blood cells and platelets) in your blood to see how Tasigna[®] is working. From time to time your doctor may also recommend taking samples of bone marrow. These tests are vital as it is important that your response to Tasigna[®] therapy is checked regularly. This will help you and your healthcare team to manage your Ph+ CML as well as possible.

Examples of how you can fit **Tasigna**[®] into your daily life



Example Routine 2

Midnight

Morning

Have breakfast

Take Tasigna®
two hour fast

Wake up

00:00 1:00 2:00 3:00 4:00 5:00 6:00 7:00 8:00 9:00 10:00 11:00 12:00

12:00 13:00 14:00 15:00 16:00 17:00 18:00 19:00 20:00 21:00 22:00 23:00 24:00

Noon

Evening

Have dinner

Take Tasigna®
after two hour
fast before
going to bed

Your Personal Schedule

Midnight

Morning

00:00 1:00 2:00 3:00 4:00 5:00 6:00 7:00 8:00 9:00 10:00 11:00 12:00

12:00 13:00 14:00 15:00 16:00 17:00 18:00 19:00 20:00 21:00 22:00 23:00 24:00

Noon

Evening

It may help to answer the following questions and put the timings on your personal schedule.

- 1. What time do you get up in the morning?** _____
- 2. Would you prefer to eat breakfast first or take your medicine first?** _____
- 3. What time do you like to eat your evening meal?** _____
- 4. What time do you go to bed normally?** _____
- 5. Are there any days where your daily routine is very different?** _____

What medicines and food should be avoided while receiving **Tasigna®**?

Tell your doctor or pharmacist before taking Tasigna® if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (also called over-the-counter medicines).

Before using any other medicines, herbal remedies or supplements you should check with your doctor. Some foods, drinks, medicines (including preparations that you can buy over-the counter without a prescription), herbal remedies and supplements can affect the amount of Tasigna® in your blood. Some of these may make Tasigna® work less well, others may increase the amount of Tasigna® in your

blood and cause unwanted and possibly severe side effects. Certain medicines should be avoided during your treatment with Tasigna® including non-prescription medications and herbal products. Some examples of these drugs are shown in the box on page 16. Please check with your healthcare team before stopping or changing any medication you are already taking.

Examples of drugs that should be avoided during your treatment with Tasigna® include, but are not limited to, the following list:

- quinidine, amiodarone: **antiarrhythmics** used to treat an irregular heart beat
- verapamil, diltiazem: **used to treat high blood pressure**
- ketoconazole, itraconazole, voriconazole, clarithromycin, telithromycin, erythromycin, ritonavir: **used to treat bacterial or fungal infections**
- cyclosporine, tacrolimus: used as **immunosuppressants**
- carbamazepine, phenobarbital, phenytoin: **used to treat seizure disorders e.g. epilepsy**
- rifampin: **used to treat a type of infection called tuberculosis (TB)**
- St. John's Wort: a **herbal product used to treat depression** and other conditions (also known as Hypericum Perforatum)
- midazolam: **used to relieve anxiety** before surgery
- warfarin: **used to treat blood coagulation disorders** (such as blood clots or thrombosis)

If you are taking any of these medicines, your doctor might prescribe alternatives that have the same effect but which do not change the amount of Tasigna® in your blood. You should also tell your doctor if you are already taking Tasigna® and you are then prescribed a new medicine you have not taken previously during Tasigna® treatment. For all the time you are on treatment with

Tasigna® you should not eat grapefruit or drink grapefruit juice or take supplements containing grapefruit extracts.



Please talk to your healthcare team before taking any other medicines or supplements or herbal remedies while you are on treatment with Tasigna®.

What should I do if I miss a dose?

If you miss a dose, take your next dose of Tasigna[®] as scheduled. **Do not take a double dose to make up for the forgotten capsules.**

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 overdose?

If you have taken more Tasigna[®] than you should have – or if someone who has not been prescribed Tasigna[®] takes your capsules, contact a doctor, pharmacist or poison centre, immediately. Show the doctor a capsule or the pack of capsules. Medical treatment may be necessary.

What are the possible side effects of Tasigna[®]?

Like all medicines, Tasigna[®] can cause side effects, although not everybody will get them. Please talk to your healthcare team about how best to manage any side effects you may have.

The most common side effects of Tasigna® are:

- low blood count (this will show up in your regular blood tests)
- nausea (feeling sick), vomiting (being sick), or abdominal (stomach) pain
- swelling of hands, ankles, feet or face
- other common side effects include rash, headache, itching, tiredness, diarrhoea, constipation and pain in joints or muscles.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment. Others can be managed with medicines or other treatments. However, in some cases the side effects can be serious. In these cases Tasigna® therapy may need to be temporarily stopped and/or the dose lowered. Your healthcare team will monitor you on a regular basis for signs or symptoms of serious side effects.

You need to let your healthcare team know if you experience any of the following symptoms, as they may be signs of a more serious side effect:

- irregular heart beat
- unexplained bleeding or bruising and/or blood in urine or stool
- shortness of breath
- yellow skin and eyes (which may be signs of a liver disorder)
- unexplained weakness.

This is not a full list of all symptoms that have been recorded in clinical trials with Tasigna[®], so it is important that you report any unusual symptoms to your healthcare team.

What are the differences between Tasigna[®] and Glivec[®]?

An important difference between Tasigna[®] and Glivec[®] is when and how the pills are taken. While Glivec[®] is usually taken once a day with or after a meal, Tasigna[®] must be taken TWICE a day while fasting (no food in your stomach) – this means that you must wait for at least 2 hours after eating before taking your Tasigna[®] and then not eat anything further for at least 1 hour after taking your pills. *(See pages 10–13 for some suggestions on how to fit your Tasigna[®] doses into your daily schedule.)*

Novartis Oncology Region Europe supported the realisation of this project.

INSIDE BACK COVER

The logo consists of a stylized circular emblem on the left, composed of two concentric purple arcs. An orange triangle points upwards from the center of the inner arc.

Tasigna[®]
(nilotinib)