



KEEP ALL MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Tasigna (Nolotinib)

What is Tasigna?

It treats chronic myeloid leukaemia (CML). It is a type of biological therapy called a protein tyrosine kinase inhibitor (TKI). Tyrosine kinases are proteins that act as chemical messengers (enzymes). They can stimulate cancer cells to grow. There are a number of different tyrosine kinases.

Tasigna blocks a tyrosine kinase protein called Bcr-Abl. The protein is made by chronic myeloid leukaemia cells that have an abnormal chromosome called the Philadelphia chromosome. Blocking this protein stops the leukaemia cells growing. 95 out of 100 people with CML (95%) have the Philadelphia chromosome.

How you have Tasigna

- Tasigna comes as red capsules. You usually take 2 capsules twice a day, 12 hours apart. You should not take them with food. You need to take them at least 2 hours before you eat and at least 1 hour after eating. Swallow them whole with a glass of water.
- If you can't swallow the whole capsules you can mix the powder from the capsule with a teaspoon of apple sauce. You need to swallow it immediately and don't use any food other than apple sauce.
- It is very important that you take capsules according to the instructions your doctor or pharmacist gave you. Whether you have a full or empty stomach, for example, can affect how much of a drug gets into your bloodstream. You should take the right dose, not more or less. And never stop taking a cancer drug without talking to your specialist first. If you miss a dose, don't take an extra dose but take the next dose at the prescribed time.
- You usually carry on taking Tasigna for as long as it works.
- The side effects associated with Tasigna are listed below. Remember that most people only have a few of them and they may be mild.

Common side effects

More than 10 in every 100 people have one or more of the side effects listed below.

- A temporary drop in the number of blood cells made by the bone marrow, causing
- An increased risk of getting an infection from a drop in white blood cells – it is harder to fight infections and you can become very ill. You may have a high temperature (fever), headaches, aching muscles, a cough, sore throat, pain passing urine or feel cold and shivery
- Tiredness and breathlessness due to a drop in red blood cells (anaemia) – you may need a blood transfusion
- Bruising more easily due to a drop in platelets – you may have nosebleeds, bleeding gums after brushing your teeth, or lots of tiny red spots or bruises on your arms or legs (known as petechia)
- Some of these side effects can be life threatening, particularly infections. You should contact your treatment team if you have any of these effects. Your doctor or nurse will check your blood counts regularly to see how well your bone marrow is working.
- Contact your treatment centre straight away if you have any of these effects or if your temperature goes above 38°C
- Skin changes in just over 2 out of 10 people (20%), including a rash or red, dry, itchy skin – this can be difficult to cope with so tell your doctor or nurse if you have it



KEEP ALL MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

- Feeling or being sick happens in about 2 out of every 10 people (20%) but is usually well controlled with anti sickness medicines
- Tiredness (fatigue) affects just under 2 in 10 people (20%) during and after treatment – most people find their energy levels are back to normal within 6 months to a year
- Headaches affect about 1 in 6 people (15%)
- Shortness of breath and a cough
- Muscle pain
- Change in blood sugar levels – you will have a blood test before treatment and regular tests during treatment to check this. You may also need to check your urine for sugar
- Loss of appetite
- Loss of fertility – you may not be able to become pregnant or father a child after treatment with this drug. Talk to your doctor before starting treatment if you think you may want to have a baby in the future. Men may be able to store sperm before starting treatment

Occasional side effects

Between 1 and 10 in every 100 people have one or more of these.

- Pain in the upper abdomen
- Eye problems – these include blurred vision, dry eyes and inflammation of the surface of the eye
- Hair thinning
- Skin flushing
- Numbness or tingling in fingers and toes can cause difficulty with fiddly things such as doing up buttons – this starts within a few days or weeks and usually goes within a few months of finishing treatment
- Constipation – your doctor or nurse may give you laxatives to help prevent this but do tell them if you are constipated for more than 3 days
- Aching in the bones or joints or the back
- Diarrhoea – drink plenty of fluids and tell your doctor or nurse if diarrhoea gets severe, or continues for more than 3 days
- Fluid build up in the body (including your legs, face or around your organs) – you may need to take tablets to reduce the amount of fluid
- Indigestion
- Pain in the hands or feet
- Dizziness and a spinning sensation
- Muscle spasms
- A feeling of the heart beating very fast (palpitations)
- Liver changes that are very mild and unlikely to cause symptoms – the liver will almost certainly go back to normal when treatment finishes, but you will have regular blood tests to check how well your liver is working
- Kidney changes that are mild and unlikely to cause symptoms may occur – they will almost certainly go back to normal when treatment ends, but you will have regular blood tests
- Weakness
- Sleeplessness and anxiety



KEEP ALL MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

- A bloated abdomen and wind (flatulence)
- Difficulty having an erection

Rare side effects

- The following side effects are very rare but tell your doctor or nurse straight away if you have them.
- Heart problems including chest pain. If you have a heart condition and need to take Tasigna you will have regular tests to check your heart
- Sudden weakness or loss of strength, fits (seizures), or sudden changes in thinking or alertness caused by a fast breakdown of cancer cells releasing substances into the blood
- Eyesight changes
- Swelling of the eyelids
- Feeling hot or cold
- Areas of skin that are red or silver and scaly, similar to psoriasis

Important points to remember

You may only have a few of these side effects and they may be mild. A side effect may get worse through your course of treatment. Or you may have more side effects as the course goes on. This depends on

- How many times you've had a drug before
- Your general health
- How much of the drug you have (the dose)
- Other drugs you are having

Coping with side effects

Talk to your doctor, pharmacist or nurse about all your side effects so they can help you manage them. They can give you advice or reassure you. Your nurse will give you a contact number to ring if you have any questions or problems. If in doubt, call them.

Other medicines and foods

Tell your doctor about any other medicines you are taking, including vitamins, herbal supplements and over the counter remedies. Some drugs can react together.

Some drugs can increase the levels of Tasigna in the body – these include some anti fungal medicines, blood thinning medicines and antibiotics. Grapefruit and grapefruit juice can also increase tasigna levels so it is important to avoid these while you are having tasigna treatment.

Some drugs and herbal products can lower the levels of tasigna – these include some antibiotics, some anti epileptic drugs, and some herbal products such as St. John's Wort.

Pregnancy and contraception

This drug may harm a baby developing in the womb. It is important not to become pregnant or father a child while you are having treatment with this drug and for at least 2 weeks afterwards. Talk to your doctor or nurse about effective contraception before starting treatment.

Breastfeeding

Do not breastfeed during this treatment because the drug may come through in the breast milk.



KEEP ALL MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Medical and dental treatment

If you need to go into hospital for any reason other than cancer, always tell the doctors and nurses that you are having chemotherapy. Give them contact details for your cancer doctor.

Talk to your cancer doctor or nurse if you think you need dental treatment. Always tell your dentist you are having chemotherapy.

Immunisations

- You should not have immunisations with live vaccines while you are having treatment or for at least 6 months afterwards. These include rubella, mumps, measles (usually given together as MMR), BCG, yellow fever and Zostavax (shingles vaccine).
- You can have other vaccines, but they may not give you as much protection as usual until your immune system has fully recovered from your treatment. It is safe to have the flu vaccine.
- It is safe for you to be in contact with other people who've had live vaccines as injections. There can be problems with vaccines you take by mouth (oral vaccines), but not many people have these now.
- So there is usually no problem in being with any baby or child who has recently had any vaccination. You might need to make sure that you aren't in contact with anyone who has had oral polio, cholera or typhoid vaccination recently, particularly if you live abroad.