

Tasigna®

nilotinib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tasigna.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au if you are in Australia and medsafe.govt.nz if you are in New Zealand.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tasigna is used for

Tasigna is used to treat chronic myeloid leukaemia (CML).

CML is a type of leukaemia in which an abnormal chromosome produces an enzyme that leads to uncontrolled growth of white blood cells. Tasigna kills the abnormal cells while leaving normal cells alone.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Tasigna is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend the use of this medicine in children and adolescents under 18 years of age.

Before you take Tasigna

When you must not take it

Do not take Tasigna if you have ever had an allergic reaction to nilotinib (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Tasigna after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return the medicine to your pharmacist.

Before you start to take it

Tell your doctor if you are pregnant or planning to become pregnant.

This medicine may be harmful to your unborn baby. If it is necessary for you to take it during pregnancy, your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding. You should not take Tasigna if you are breast-feeding as it may harm your baby.

Tell your doctor if you have ever had any of the following medical problems or procedures:

- kidney or liver problems
- problems with your heart
- heart attack, chest pain (angina), stroke, or leg pain (could be problems with your leg blood flow)
- high blood pressure
- lower than normal blood levels of potassium or magnesium
- high cholesterol or lipid levels in blood
- high sugar levels in blood
- pancreatitis (inflamed pancreas)
- surgical procedure involving the removal of the entire stomach (total gastrectomy)
- hepatitis B infection. As during treatment, hepatitis B (an infection of the liver) may become active again.

Your doctor may want to take special precautions in that case.

Tell your doctor if you have an intolerance to lactose.

This medicine contains lactose.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Tasigna may interfere with each other. These include:

- St. John's Wort, a herbal medicine found in many products that you can buy without a prescription
- some chemotherapy medicines such as daunorubicin, doxorubicin, epirubicin, mitozantrone
- antibiotic medicines such as rifampicin, erythromycin, clarithromycin, telithromycin, moxifloxacin
- antifungal medicines such as ketoconazole, itraconazole, voriconazole
- antiviral medicines used to treat HIV/AIDS such as ritonavir
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone
- medicines used as sedatives such as midazolam
- anti-arrhythmic medicines used to treat irregular heart beat such as amiodarone, disopyramide, procainamide, sotalol
- medicines that may affect the function of the heart such as chloroquine, halofantrine, haloperidol, methadone, bepridil
- alfentanil and fentanyl - used to treat pain and used as a sedative before or during surgery or medical procedure
- cyclosporine, sirolimus and tacrolimus - medicines that suppress the "self-defense" ability of the body to fight infections - commonly used to prevent the rejection of transplanted organs such as liver, heart and kidney
- dihydroergotamine and ergotamine - medicines used to

treat migraine and certain headaches

- medicines used to lower cholesterol ("statins") such as simvastatin.

In addition, tell your doctor or pharmacist before taking Tasigna if you are taking antacids (medicines against heartburn) or other medicines that suppress gastric acid secretion. These medications need to be taken separately from Tasigna:

- medicines that suppress gastric acid secretion called H2 blockers decrease the production of acids in the stomach. These should be taken approximately 10 hours before and approximately 2 hours after you take Tasigna;
- antacids such as those containing aluminum hydroxide, magnesium hydroxide and simethicone neutralize the high acidity of the stomach. These should be taken approximately 2 hours before or approximately 2 hours after you take Tasigna.

These medicines should be avoided during your treatment with Tasigna. If you are taking any of these, you may need to take different amounts of these medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Tasigna

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

For patients newly diagnosed with CML, the usual dose is two capsules of 150 mg (300 mg) taken twice a day.

For CML patients no longer benefiting from previous treatment for CML, the usual dose is two capsules of 200 mg (400 mg) taken twice a day. Two capsules in the morning and two in the evening.

Your doctor may direct you to take a higher or lower dose, depending on your response to Tasigna.

How to take it

Take Tasigna in the morning and the evening, about 12 hours apart.

Tasigna must not be taken with food. Take it at least 2 hours after eating. Do not eat for at least 1 hour after taking it.

This will help you absorb the right amount of medicine to effectively treat your condition.

For example, your day might look a bit like this:

7 am: wake up and take your 1st dose of Tasigna

8 am: breakfast

Usual daily activities

5pm: begin fasting in preparation for your next dose of Tasigna.

7 pm: take your 2nd dose of Tasigna

8 pm: dinner

Take the capsules with a large glass of water.

If you are unable to swallow capsules, you may mix the content of each capsule in one teaspoon of applesauce (pureed apple) and swallow the mixture immediately.

This will help to avoid irritating the lining of your oesophagus (food pipe) and stomach.

For the best effect, take the capsules at about the same time each day.

Taking them at the same time each day will help you to remember to take them.

If your doctor recommends to stop Tasigna

Your doctor will regularly check your treatment with specific monitoring tests. If you have been on Tasigna for 3 years, have achieved a certain response to treatment for at least one year and have a certain type of CML, your doctor may decide whether you should continue or stop taking Tasigna. If you are told to stop taking Tasigna, your doctor will continue to carefully monitor your CML before, during and after cessation. Close monitoring is needed in case you get worse and you may need to re-start Tasigna.

How long to take it

Continue taking Tasigna every day for as long as your doctor prescribes.

Your doctor will keep a close check on you to make sure you are still benefiting from treatment.

If you forget to take it

If you miss a dose, skip the dose you missed and take your next dose as scheduled. Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 131 126 in Australia or 0800 764 766 in New Zealand) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Tasigna. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Tasigna

Things you must do

Call your doctor right away or as soon as possible if you have fainted or have an irregular heartbeat while taking Tasigna as these may be due to a serious heart condition. Uncommon cases of sudden death have been reported in patients receiving Tasigna.

Call your doctor right away or as soon as possible if you develop chest pain or discomfort, numbness or weakness or problems with walking or talking, or pain, numbness, discoloration or a cool feeling in arms or legs.

Make sure you follow your doctor's instructions carefully and keep all appointments.

You will need regular follow-up to make sure the treatment is working. Regular blood tests, ECG test and weight checks can also find side effects before they become serious.

Make sure you use a highly effective method of contraception to prevent pregnancy during treatment with Tasigna and for up to two weeks after ending treatment with Tasigna. Tell your doctor immediately if you become pregnant while you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tasigna.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Tasigna.

Things you must not do

Do not give this medicine to anyone else even if their condition seems to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Do not eat or drink products and juices containing grapefruit, star

fruit, pomegranate, seville oranges and other similar fruits at any time while you are being treated with Tasigna.

It may interact with Tasigna and affect how your body uses this medicine.

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Tasigna affects you.

This medicine may cause dizziness or light-headedness in some people. Make sure you know how you react to it before you drive a car, operate machinery or do anything that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tasigna.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- nausea, constipation, diarrhoea, vomiting
- headache
- tiredness
- muscle pain
- itching, rash, hives
- hair loss
- upper respiratory tract infections
- abdominal pain, stomach discomfort after meals, flatulence
- bone pain, pain in joints, muscle spasms
- pain including back pain, neck pain and pain in extremity, pain

- or discomfort in the side of the body
- skin reddening, dry skin, acne
- excessive sweating, night sweats, hot flushes
- weight decrease or increase, decreased appetite, disturbed sense of taste
- difficulty sleeping, depression, anxiety, confusion, disorientation
- nose bleed
- urinating frequently
- generally feeling unwell
- eye itching, dry eye
- dry mouth, mouth sores
- erection disorder, breast enlargement in men
- flu-like symptoms, muscle weakness
- runny or stuffy nose, sneezing, sore throat
- oral or vaginal thrush
- muscle and joint stiffness
- musculoskeletal pain such as: muscle pain, pain in hand or foot, pain in joints, bone pain and spinal pain upon stopping treatment with Tasigna. These symptoms may be more frequent than prior to your treatment being stopped (refer to If your doctor recommends to stop Tasigna)
- visual disturbances
- feeling body temperature change (including feeling hot, feeling cold)

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you get any of the following side effects:

- chest pain or discomfort, high blood pressure, irregular heart rhythm (fast or slow), palpitations, fainting, blue discolouration of the lips, gums or skin
- rapid weight gain, swelling of face, hands, ankles or feet
- difficulty or painful breathing, cough, wheezing with or without fever

- fever, easy bruising, frequent infections
- weakness or paralysis of face or limbs, difficulty speaking, severe headache, seeing, feeling or hearing things that are not there, loss of consciousness, confusion, disorientation, trembling, sensation of tingling (pins and needles), pain or numbness in fingers and toes
- thirst, dry skin, irritability, dark urine, passing little urine, difficulty or pain in passing urine, urge to urinate frequently, blood in urine
- blurred vision, loss of vision, blood in eye, increased sensitivity of the eyes to light, eye pain or redness, swelling and itching of the eyelids, decreased sharpness of vision, eye irritation
- swelling and pain in one part of the body
- abdominal pain, vomiting blood, black or bloody stools, constipation, heartburn, stomach acid reflux, swelling or bloating of the stomach
- severe upper (middle or left) abdominal pain
- yellowing of the skin and eyes, nausea, loss of appetite, dark coloured urine
- rash, painful red lumps, pain in joints and muscles
- bulging eyes, fast heartbeat, weight loss, swelling at front of the neck
- weight gain, tiredness, hair loss, muscle weakness, feeling cold
- dizziness or spinning sensation
- excessive thirst, passing large amounts of urine, increased appetite with weight loss, tiredness (signs of a high level of sugar in the blood)
- severe headaches often accompanied by nausea, vomiting and sensitivity to light (signs of migraine)
- nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint

discomfort associated with abnormal laboratory results (such as high potassium, uric acid, and phosphorous levels and low calcium levels in the blood).

- pain or discomfort, weakness, or cramping in leg muscles which may be due to decreased blood flow, ulcers that heal slowly or not at all and noticeable changes in colour (blueness or paleness) or temperature (coolness) as these symptoms could be signs of artery blockage in the affected limb (leg or arm) and digits (toes and fingers)
- fever, skin rash, joint pain and swelling as well as tiredness, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stools and dark urine (potential signs of hepatitis B reactivation).

Some side effects can only be found when your doctor does tests from time to time to check your progress.

During Tasigna treatment, you may also have some abnormal blood test results such as low level of blood cells (white cells, red cells, platelets), high blood level of lipase or amylase (pancreas function), high blood level of bilirubin (liver function), high blood level of creatinine (kidney function), high level of potassium or low level of magnesium, low or high blood level of Insulin (an enzyme regulating blood sugar level), high level of fats in the blood.

Your heart rate will also be checked using a machine that measures electrical activity of the heart (a test called an "ECG").

The above side effects may be serious. You may need urgent medical attention. Serious side effects are generally rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed here or not yet known may happen in some

people. Some of these side effects can only be found by laboratory testing.

After taking Tasigna

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place.
- Do not store Tasigna or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Tasigna 150 mg is a white to slightly yellowish powder in red opaque hard gelatin capsules, size 1 with black axial imprint "NVR/BCR".

Tasigna 200 mg is a white to slightly yellowish powder in light yellow opaque hard gelatin capsules, size 0 with red axial imprint "NVR/TKI".

In Australia, Tasigna (150mg and 200mg) is available in 28's (weekly), and 120's (monthly) packs.

The weekly pack contains 2 calendar cards (day time and night time) of 14 capsules.

The monthly pack consists of 3 packs of 40 capsules.

In New Zealand, Tasigna 200mg is available.

Ingredients

Tasigna capsules contain 150 mg or 200 mg of nilotinib. Tasigna capsules also contain:

- lactose
- crospovidone
- silica - colloidal anhydrous
- magnesium stearate
- poloxamer
- titanium dioxide
- gelatin
- iron oxide yellow
- iron oxide red
- printing ink (150 mg - black; 200 mg - red)

Sponsor

Tasigna is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
(ABN 18 004 244 160)
54 Waterloo Road
Macquarie Park NSW 2113
Telephone 1 800 671 203
Website: www.novartis.com.au

Tasigna is supplied in New Zealand by:

Novartis New Zealand Limited
109 Carlton Gore Road
Newmarket
Auckland 1023
PO Box 99102
Newmarket
Auckland 1149
Telephone: 0800 354 335

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