

**Read all of this leaflet carefully before you start using TASIGNA®**

Keep this leaflet. You may need to read it again.  
TASIGNA has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.  
If you have further questions, please ask your doctor or your pharmacist.  
If any of the side-effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**SCHEDULING STATUS:**

**S4**

**PROPRIETARY NAME AND DOSAGE FORM:**

TASIGNA® 200 mg capsule

TASIGNA® 150 mg capsule

**WHAT TASIGNA CONTAINS:**

The active substance is nilotinib.

Each capsule contains either 200 mg or 150 mg nilotinib.

The other ingredients are lactose, crospovidone, poloxamer 188, colloidal silicon dioxide and magnesium stearate. The capsule shell is composed of gelatin, titanium dioxide, iron oxide yellow and iron oxide red as well as a printing ink.

**WHAT TASIGNA IS USED FOR:**

TASIGNA is used to treat a type of leukaemia called Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML). CML is a cancer of the blood which makes the body produce too many abnormal white blood cells.

TASIGNA is used in patients with newly diagnosed CML or patients with CML who are no longer benefiting from previous treatment including imatinib. It is also used in patients who experienced serious side-effects with previous treatment and are not able to continue taking it.

**BEFORE YOU TAKE TASIGNA:**

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

**Do not take TASIGNA:**

If you are allergic (hypersensitive) to nilotinib or any of the other ingredients of (see **What TASIGNA contains**)

If you think you may be allergic, tell your doctor without taking TASIGNA.

**Take special care with TASIGNA:**

- if you have a heart disorder, such as an abnormal electrical signal called "prolongation of the QT interval"
- if you are being treated with medicines that affect the heart beat (antidysrhythmics) or the liver (see "Taking other medicines with TASIGNA")
- if you suffer from a low level of potassium or magnesium in your blood
- if you have been treated with a medicine of the type called anthracyclines (frequently used in leukaemia therapy)
- if you have a liver disorder
- if you have had pancreatitis (inflamed pancreas)

If any of these apply to you, tell your doctor before taking TASIGNA.

**Taking TASIGNA with food and drink:**

- Do not take TASIGNA with food.
- Take the capsules at least two hours after any food and then wait at least one hour before eating again.
- Do not drink grapefruit juice or eat grapefruit while on TASIGNA. It may increase the amount of TASIGNA in the blood, possibly to a harmful level.

**Older people (age 65 years and over):**

TASIGNA can be used by people aged 65 years and over at the same dose as for other adults.

**Children and adolescents (below the age of 18 years):**

There is no experience with the use of TASIGNA in children and adolescents and hence should not be used by these patients.

**Pregnancy and breastfeeding mothers:**

**If you are pregnant or breastfeeding your baby while taking TASIGNA, please consult your doctor, pharmacist or other health care professional for advice.**

- TASIGNA is not recommended during pregnancy.
- Women of child-bearing potential or sexually active men must use effective birth control while taking TASIGNA.
- Breastfeeding is not recommended during treatment with TASIGNA. Tell your doctor if you are breastfeeding.

**Driving and using machines:**

If you experience side-effects (such as dizziness or visual disorders) with a potential impact on the ability to safely drive or use any tools or machines after taking TASIGNA, you should refrain from these activities.

**Important information about some of the ingredients of TASIGNA:**

TASIGNA contains lactose (milk sugar). If you know that you have intolerance to lactose, tell your doctor before taking TASIGNA.

**Taking other medicines with TASIGNA:**

TASIGNA may interfere with some other medicines.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of TASIGNA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare profession for advice.

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. This includes in particular:

- antidysrhythmics - used to treat irregular heart beat;
- chloroquine, halofantrine, clarithromycin, haloperidol, methadone – medicines that may have an unwanted effect on the function of the heart.
- ketoconazole, itraconazole, voriconazole, moxifloxacin, clarithromycin, telithromycin - used to treat infections;
- ritonavir - an anti-HIV medicine from the class “antiproteases”;
- carbamazepine, phenobarbital, phenytoin - used to treat epilepsy;
- rifampicin - used to treat tuberculosis;
- St. John’s Wort - a herbal product used to treat depression and other conditions (also known as *Hypericum Perforatum*);
- midazolam - used to relieve anxiety;
- warfarin - used to treat blood coagulation disorders (such as blood clots or thromboses)

These medications should be avoided during your treatment with TASIGNA. If you are taking any of these, your doctor might prescribe other medicines.

You should also tell your doctor if you are already taking TASIGNA and you are prescribed a new medicine you have not taken previously during TASIGNA treatment.

**HOW TO TAKE TASIGNA:**

Always take TASIGNA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not share medicines prescribed for you with others.

**Monitoring your TASIGNA treatment:**

You will have regular tests including blood tests during treatment. These will monitor the amount of blood cells (white blood cells, red blood cells and platelets) in your body to see how TASIGNA is tolerated. If you have any questions about how TASIGNA works or why it has been prescribed for you, ask your doctor.

**How much TASIGNA to take:**

The starting dose is 2 capsules twice a day either 300 mg or 400 mg twice a day depending on your exact condition. Always take TASIGNA exactly as your doctor has told you.

**When to take TASIGNA:**

Take the capsules twice a day (approximately every 12 hours), at least 2 hours after any food. Then wait for at least 1 hour before eating again.

If you have questions about when to take TASIGNA, talk to your doctor or pharmacist.

Taking TASIGNA at the same time each day will help you remember when to take your capsules.

**How to take TASIGNA:**

- Do not take any food together with the capsules.
- Swallow the capsules whole with water.
- If you are unable to swallow the capsules, disperse the contents of each capsule in one teaspoon of applesauce (pureed apple) and take immediately. Not more than one teaspoon of applesauce and no food other than applesauce must be used.

**If you take more TASIGNA than you should:**

If you have taken more TASIGNA than you should have, or if someone else accidentally takes your capsules, contact a doctor or the hospital for advice straight away. Show them the pack of capsules. Medical treatment may be necessary.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, take the patient to the nearest hospital or poison control centre

**If you forget to take TASIGNA:**

If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for the forgotten capsules.

**If you stop taking TASIGNA:**

Do not stop taking TASIGNA unless your doctor tells you to. If you have any further questions on the use of TASIGNA, ask your doctor or pharmacist.

**POSSIBLE SIDE EFFECTS**

TASIGNA can cause side-effects

Not all side-effects reported for TASIGNA are included in this leaflet.

Should your general health worsen while taking TASIGNA, please consult your doctor, pharmacist or other health care professional for advice.

**Some side effects can be serious:**

- rapid weight gain, swelling of hands, ankles, feet or face
- chest pain, high blood pressure, irregular heart rhythm
- difficulty breathing, cough, wheezing, swelling of the feet or legs
- fever, sore throat, mouth sores, weakness, bruising, frequent infections
  
- weakness or paralysis of limbs or face, difficulty speaking, severe headache, seeing, feeling or hearing things that are not there
- thirst, dry skin, irritability, dark urine, decreased urine output
- blurred vision, loss of vision, visible bleeding in white of eye
- swelling and pain in one part of the body
- abdominal pain, nausea, vomiting of blood, black stools, constipation, swollen abdomen
- yellow skin and eyes, nausea, loss of appetite, light-coloured urine

- rash, painful red lumps, pain in joints and muscles
- excessive thirst, high urine output, increased appetite with weight loss, tiredness

If you get any of these, tell your doctor straight away.

#### **Frequent side-effects**

- nausea, constipation, diarrhoea
- headache
- tiredness
- itching, rash
- low level of white blood cells, red blood cells or platelets and high level of lipase in the blood (changes in blood test results)
- vomiting, abdominal pain, stomach discomfort after meals, flatulence bloating of the stomach.
- bone pain, pain in joints, muscle spasms, muscle pain
- skin reddening, dry skin
- weight decrease or increase
- hair loss
- insomnia sleeplessness
- night sweats, excessive sweating, hot flushes
- dizziness, generally feeling unwell, spinning sensation
- tingling or numbness
- voice disorder
- abnormal liver function test and other changes in blood test results such as high level of potassium or low level of magnesium
- palpitations (sensation of rapid heart beat)

If any of these affects you severely, tell your doctor.

#### **Less frequent side-effects**

- decreased or increased skin sensitivity
- eye irritation, swelling, discharge, itching or redness, dry eye (signs of eye disorders)
- dry mouth
- heartburn, swelling or bloating of the abdomen
- breast pain
- nose bleed
- decrease or increase appetite
- anxiety
- difficulty and pain when passing urine, exaggerated sense of needing to urinate
- inability to achieve or maintain an erection
- breast enlargement in men
- flu-like symptoms
- trembling
- decreased sharpness of vision
- frequent urine output
- abnormal kidney function test results
- sensitivity to light
- fast heart beat, bulging eyes, swelling at front of the neck
- depression

If any of these affects you severely, tell your doctor.

#### **The following other side effects have also been reported**

- confusion, disorientation.
- sensation of numbness or tingling in fingers and toes
- increased sensitivity of the eyes or the skin to light
- eye pain or redness, pain, swelling, and itching of the eyelids
- difficulty hearing, ear pain
- joint stiffness, muscle weakness

- unconsciousness
- blood in urine
- weight gain, tiredness, hair loss, muscle weakness, feeling cold

If any of these affects you, tell your doctor.

If you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

**STORAGE AND DISPOSAL INFORMATION:**

Keep out of the reach and sight of children.

Do not use TASIGNA after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store at or below 30°C.

Store in the original package in order to protect from moisture.

Do not use any pack that is damaged or shows signs of tampering.

**PRESENTATION:**

TASIGNA comes in packs of 28 or 112 capsules in colourless, transparent PVC/PVDC (polyvinylchloride/polyvinylidene chloride) blisters with an aluminium foil backing. The blisters are packed into cardboard cartons.

Not all pack sizes may be available.

**IDENTIFICATION:**

TASIGNA® 200 mg capsule: White to yellowish powder, in light yellow capsules with red imprint "NVR/TKI" on each capsule.

TASIGNA® 150 mg capsule: White to yellowish powder, in red capsules with a black imprint "NVR/BCR" on each capsule.

**REGISTRATION NUMBERS:**

TASIGNA® 200 mg capsule: 41/26/0973

TASIGNA® 150 mg capsule: 45/26/0410

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION:**

NOVARTIS SOUTH AFRICA (PTY) LTD

Magwa Crescent West,

Waterfall City,

Jukskei View,

Johannesburg

2090

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01 March 2013