Tasigna®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TASIGNA?

TASIGNA contains the active ingredient nilotinib. TASIGNA is used to treat chronic myeloid leukaemia (CML)

For more information, see Section 1. Why am I using TASIGNA? in the full CMI.

2. What should I know before I use TASIGNA?

Do not use if you have ever had an allergic reaction to TASIGNA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use TASIGNA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TASIGNA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use TASIGNA?

- If you have been newly diagnosed with CML the usual dose of TASIGNA is two capsules of 150 mg (300 mg) twice daily. If you are no longer doing well from previous treatment for CML, the usual dose is two capsules of 200 mg (400 mg) twice daily.
- You should take TASIGNA in the morning and evening, approximately 12 hours apart.
- You must not take TASINGA with food. Do not eat at least 2 hours before and 1 hour after taking TASIGNA.

More instructions can be found in Section 4. How do I use TASIGNA? in the full CMI.

5. What should I know while using TASIGNA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using TASIGNA. • Have regular blood tests, heart and weight checks while using TASIGNA. • Avoid becoming pregnant while using TASIGNA and for 2 weeks after you stop using it.
Things you should not do	• Do not stop using this medicine suddenly (unless your doctor tells you to). • Do not drink products and juices containing grapefruit juice, star fruit, pomegranate, seville oranges and other similar fruits while using TASIGNA.
Driving or using machines	• It is not known if TASIGNA will influence your ability to drive and use machines. • Be cautious when driving or using machines in case you feel dizzy or tired while using TASIGNA.
Drinking alcohol	• There are no known interactions between TASIGNA and alcohol.
Looking after your medicine	• Store below 30°C. • Keep out of reach of children.

For more information, see Section 5. What should I know while using TASIGNA? in the full CMI.

6. Are there any side effects?

Common side effects include headache, decreased appetite, feeling sick, vomiting, constipation, diarrhoea, tummy pain, rash, hair loss, dry skin, pain in muscles or joints, tiredness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

TASIGNA® (TAS-inn-yah)

Active ingredient(s): *nilotinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TASIGNA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TASIGNA.**

Where to find information in this leaflet:

1. Why am I using TASIGNA?
2. What should I know before I use TASIGNA?
3. What if I am taking other medicines?
4. How do I use TASIGNA?
5. What should I know while using TASINGA?
6. Are there any side effects?
7. Product details

1. Why am I using TASIGNA?

TASIGNA contains the active ingredient nilotinib. TASIGNA belongs to a group of medicines call tyrosine kinase inhibitors. It kills cancerous white blood cells that contain a particular kind of tyrosine kinase, while leaving normal cells alone.

TASIGNA is used to treat chronic myeloid leukaemia (CML). CML is a type of leukaemia.

2. What should I know before I use TASIGNA?

Warnings

Do not use TASIGNA if:

- you are allergic to nilotinib, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction can include difficulty breathing, wheezing, swelling of the face, lips or tongue and rash.

Check with your doctor if you:

- Have or have had problems with your heart, previous heart attack, or chest pain (angina)
- Have lower than normal blood levels of potassium or magnesium
- Have high blood cholesterol or lipid levels
- Have high blood sugar levels
- Have liver or kidney problems
- Have had hepatitis B infection
- Have had inflammation of the pancreas (pancreatitis)
- Have had surgery to remove your entire stomach (total gastrectomy)
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or intend to become pregnant. TASIGNA may harm an unborn baby. Your doctor will discuss with you what is best for you and your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not take TASIGNA if you are breastfeeding and for 2 weeks after your last dose of TASIGNA.

Contraception

You should avoid becoming pregnant while using TASIGNA and for 2 weeks after you stop using it. Ask your doctor or pharmacist for options of effective birth control.

Use in children

TASIGNA is not recommended for use in children and adolescents under 18 years of age. It may cause slower than normal growth in some children and adolescents.

3. What if I am taking other medicines?

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

Some medicines may interfere with TASIGNA and affect how it works such as:

- St John's Wort, a herbal medicine that you can buy without a prescription
- Antibiotic medicines such as clarithromycin, moxifloxacin, rifampicin
- Antifungal medicines such as itraconazole, ketoconazole, voriconazole
- Antiviral medicines used to treat HIV/AIDS such as ritonavir
- Medicines used to treat epilepsy such as carbamazepine, phenobarbital, phenytoin
- Medicines used to relax or calm you or help you sleep (sedatives) such as midazolam
- Medicines used to treat irregular heart beat such as amiodarone, disopyramide, sotalol
- Medicines that may affect the function of the heart such as chloroquine, haloperidol, methadone
- Medicines such as alfentanil and fentanyl, that are used to treat pain or as a sedative before or during surgery or a medical procedure
- Medicines such as ciclosporin, sirolimus and tacrolimus, that decrease the body's ability to fight infection and are commonly used to prevent rejection of transplanted organs
- Antacids, such as those containing aluminium hydroxide, magnesium hydroxide and simethicone, neutralise the high acidity of the stomach and should

be taken approximately 2 hours before and approximately 2 hours after you take TASIGNA.
- H2 blockers, such as famotidine and nizatidine, should be taken approximately 10 hours before and approximately 2 hours after you take TASIGNA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TASIGNA.

4. How do I use TASIGNA?

How much to take

- If you have been newly diagnosed with CML the usual dose of TASIGNA is two capsules of 150 mg (300 mg) twice daily.
- If you are no longer doing well from previous treatment for CML, the usual dose is two capsules of 200 mg (400 mg) twice daily.
- Follow the instructions provided and use TASIGNA until your doctor tells you to stop.

When to take TASIGNA

- TASIGNA should be taken in the morning and evening, approximately 12 hours apart.
- TASIGNA must not be taken with food. Do not eat for at least 2 hours before and at least 1 hour after taking TASIGNA.

How to take TASIGNA

- Swallow TASIGNA capsules whole 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). Swallow the mixture immediately. Do not use more than one teaspoon of applesauce and do not use any other food other than applesauce.

If you forget to take TASIGNA

TASIGNA should be taken regularly at the same time, twice a day. If you miss your dose at the usual time, take it as soon as you remember and then take the next capsule as usual.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you have trouble remembering when to take TASIGNA, keep a treatment diary, or ask your doctor or pharmacist for some hints.

Do not stop taking TASIGNA or change your dose without talking to your doctor.

If you take too much TASIGNA

If you think that you have taken too much TASIGNA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TASIGNA?

Things you should do

- Have regular blood tests, heart and weight checks as directed by your doctor.
- Avoid becoming pregnant while using TASIGNA and for 2 weeks after you stop using it.

Call your doctor straight away if you:

- Become pregnant or think you may be pregnant.
- Have fainted or have an irregular heart beat while using TASIGNA.
- Develop chest pain or discomfort, numbness or weakness, problems with walking or talking, or pain, numbness, change in colour or a cool feeling in your arms or legs.

Remind any doctor, dentist or pharmacist you visit that you are using TASIGNA.

Things you should not do

- Do not stop using this medicine unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Foods and drinks to avoid

- Do not eat or drink products and juices that contain grapefruit juice, star fruit, pomegranate, seville oranges or other similar fruits while you are being treated with TASIGNA.

Additional tests

Your doctor may do some blood tests such as checking blood cells (white blood cells, red blood cells and platelets), electrolytes (e.g., potassium and magnesium), sugar levels and cholesterol or lipid levels in your body from time to time to make sure TASIGNA is working and to prevent unwanted side effects. Your kidneys, liver, heart, blood pressure will also be checked regularly.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TASIGNA affects you.

TASIGNA may cause tiredness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

There are no known interactions between TASIGNA with alcohol.

Looking after your medicine

- Store below 30°.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

If your doctor recommends you stop using TASIGNA

Your doctor will regularly check your treatment with specific monitoring tests.

If you have been taking TASIGNA for 3 years, have achieved a certain response to treatment for at least 1 year and have a certain type of CML, your doctor may tell you to stop taking TASIGNA.

Your doctor will continue to monitor your CML. If you get worse, you may need to start using TASIGNA again.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Tummy problems: • Tummy pain or discomfort • Feeling sick • Vomiting • Constipation • Diarrhoea • Wind or gas **Skin problems:** • Itching • Rash • Dry skin • Hair loss • Warts • Acne **Eye problems:** • Eye infection	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.**
• Dry eye **General:** • Headache • Tiredness/lack of energy • Muscle, bone or joint pain • Pain in hands or feet • Muscle spasms/weakness • Tingling feeling or loss of sensation • Swelling of arms, legs, hands or feet • Upper respiratory tract infections • Depression • Anxiety • Trouble sleeping • Dizziness or light-headed • Hot flushes or night sweats • Frequent wee	

Serious side effects

Serious side effects	What to do
Heart problems: • Chest pain or discomfort • Irregular heart beat or fast heart beat **Lung problems:** • Difficult or painful breathing • Change in colour (blue) of lips, gums or skin **General:** • Fever, severe or frequent infections, unexplained bleeding or weakness • Weakness, numbness or paralysis of face, limbs, fingers or toes • Swelling and pain in one part of the body • Severe upper tummy pain • Blurred vision, double vision, decreased sharpness of vision, flashes of light in the eye, swelling or blood in the eye • Vomiting blood, black or bloody poo, pale poo • Yellowing of the skin and eyes • Difficulty or pain when you wee , need to wee frequently, blood in wee, abnormal wee colour or cloudy wee • Painful red lumps or blisters on the skin, reddening or peeling of skin, increased sensitivity of the	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
skin to light, changes in skin colour • Weight gain, loss of appetite, or increased appetite with weight loss, tiredness	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TASIGNA contains

Active ingredient (main ingredient)	Nilotinib
Other ingredients (inactive ingredients)	Lactose Colloidal anhydrous silica Crospovidone Magnesium stearate Poloxamer Gelatin Iron oxide red Iron oxide yellow Titanium dioxide Printing ink (150 mg: black; 200 mg: red)
Potential allergens	Galactose Milk Sugars as lactose Sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What TASIGNA looks like

TASIGNA is supplied as capsules in blister packs.

TASIGNA 150 mg capsules contain a white to slightly yellowish powder in red opaque hard gelatin capsules, size 1 with black axial imprint "NVR/BCR" (AUST R 171498).

TASIGNA 200 mg capsules contain a white to slightly yellowish powder in light yellow opaque hard gelatin capsules, size 0 with red axial imprint "NVR/TKI" (AUST R 133086).

TASIGNA 150 mg and 200 mg capsules are available in packs of 28 capsules (weekly)* and 120 capsules (monthly). The weekly pack contains 14 capsules on 2 calendar cards (day time and night time). The monthly pack contains 3 packs of 40 capsules.

*Not all pack sizes may be marketed.

Who distributes TASIGNA

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

Web site: www.novartis.com.au

TASIGNA is supplied in New Zealand by:

NOVARTIS New Zealand Ltd

PO Box 99102, Newmarket

Auckland 1149, New Zealand

Telephone: 0800 354 335

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