Glivec®

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 Glivec?

Glivec contains the active ingredient imatinib. Glivec is used to Glivec is used to treat children and adults who have certain types of cancer and leukemia.

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

2. What should I know before I use Glivec?

Do not use if you have ever had an allergic reaction to Glivec 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 Glivec? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Glivec 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 Glivec?

- Your doctor will tell you exactly how many tablets of Glivec to take
- Follow the instructions provided and use Glivec until your doctor tells you to stop

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

5. What should I know while using Glivec?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Glivec. • Have regular check-ups to make sure the treatment is working

Things you should not do	• Do not stop using this medicine suddenly (unless your doctor tells you to)
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Glivec affects you
Drinking alcohol	• There are no known interactions between Glivec and alcohol
Looking after your medicine	• Store it in a cool dry place away from moisture, heat or sunlight • Keep out of reach of children

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

6. Are there any side effects?

Common side effects include headache, dizziness, light-headedness or vertigo, upset stomach, nausea (feeling sick), vomiting, diarrhoea, constipation, rash, eczema, itchy or dry skin, skin darkening or lightening, symptoms of sunburn which happens more quickly than normal, noticeable swelling, stiffness in joints or muscles, pain in bones or along veins, weakness, feeling generally

unwell, numbness, tingling in fingers and toes, change in sense of taste, irritated eyes, blurred vision, ringing in the ears, changes in appetite and weight, hair loss, throat pain, cough or cold symptoms, loss of interest in sex, problems with sexual function, breast enlargement, nipple pain, painful periods, slowing of growth in children and adolescents

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.

Glivec®

Active ingredient(s): *imatinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Glivec. **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 Glivec.**

Where to find information in this leaflet:

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

1. Why am I using Glivec?

Glivec contains the active ingredient imatinib. Glivec belongs to a group of anti-cancer medicines known as tyrosine kinase inhibitors.

Glivec is used to treat children and adults who have certain types of cancer and leukemia, including chronic myeloid leukaemia (CML) and

acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL).

Glivec is also used to treat adults for:

Myelodysplastic / myeloproliferative diseases (MDS/ MPD).

These are a group of blood diseases in which some blood cells start growing out of control.

Aggressive systemic mastocytosis (ASM).

It is a cancer in which certain blood cells, called "mast" cells, grow out of control.

Hypereosinophilic syndrome (HES) and or chronic eosinophilic leukaemia (CEL).

These are blood diseases in which some blood cells, named "eosinophils", start growing out of control.

Gastro-intestinal stromal tumours (GIST).

This is a type of cancer of the stomach and bowels. This cancer affects the tissue that surrounds the stomach and bowels and the cells grow uncontrollably.

Dermatofibrosarcoma protuberans (DFSP).

DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control.

Glivec works by slowing the growth of and killing cancer cells while leaving normal cells alone.

2. What should I know before I use Glivec?

Warnings

Do not use Glivec if:

- you are allergic to imatinib, or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

If you experience an allergic reaction, stop using the medicine and inform your doctor or pharmacist immediately.

- Some of the symptoms of an allergic reaction may include:
- 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

Check with your doctor if you:

- have any other medical conditions
- 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

Check with your doctor if you are pregnant or intend 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 let you know.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if the active ingredient, imatinib, passes into the breast milk. Breastfeeding is not recommended because this medicine could affect 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
- you have had your thyroid gland removed
- hepatitis B infection. As during treatment with Glivec, hepatitis B may become active again.

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

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 Glivec and affect how it works.

- St. John's wort, a herbal medicine found in many products that you can buy without a prescription
- paracetamol, a medicine found in many common pain relievers and cold remedies (e.g. Panadol®, Panadeine®, Codral®, Tylenol®) which are known to be associated with liver toxicity.
- antibiotic medicines such as rifampicin, ketoconazole, erythromycin, clarithromycin, itraconazole
- antiviral medicines used to treat HIV/AIDS
- dexamethasone, a steroid medicine
- medicines for high cholesterol, such as simvastatin
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone
- warfarin, a medicine used to prevent blood clots
- some medicines used to treat mental disorders and depression
- some medicines used to treat high blood pressure and heart problems
- cyclosporin

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

Glivec may interfere with how well other medicines work. Glivec may affect how well methotrexate (used to treat arthritis or psoriasis) works, especially when methotrexate is given in high doses.

4. How do I use Glivec?

How much to take

- Your doctor will tell you exactly how many tablets of Glivec to take
- Do not exceed the recommended dose prescribed by your doctor
- Follow the instructions provided and use Glivec until your doctor tells you to stop
- Your doctor may direct you to take a higher or lower dose or stop treatment depending on how your body responds to Glivec.
- Glivec is usually taken as a single dose each day. However, your doctor may want you to take them in two doses, one in the morning and one in the evening

When to take Glivec

- Take Glivec every day; at the same time, with water and food for as long as your doctor recommends

How to take Glivec

- Take Glivec with a large glass of water and food. This will help avoid stomach irritation
- If you are unable to swallow the tablets:
- Put the required tablets in a glass of water or apple juice (approximately 50 mL for a 100 mg tablet or 200 mL for a 400 mg tablet)
- Stir with a spoon to completely dissolve the tablets
- Drink immediately

If you forget to use Glivec

Glivec should be taken regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as you remember, then continue with your normal schedule.

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 take too much Glivec

If you think that you have taken too much Glivec, 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 Glivec?

Things you should do

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

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

Use a method of contraception to prevent pregnancy during treatment and for 15 days after ending treatment.

Some children taking Glivec may have slower than normal growth. Growth will be monitored at regular visits by your doctor.

Call your doctor straight away if you

- Become pregnant or think you might be pregnant
- Think you might be having an allergic reaction to Glivec treatment

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

Things you should not do

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

Drinking grapefruit juice

Avoid drinking grapefruit juice while you are being treated with Glivec. Grapefruit juice may interact with Glivec and affect how your body uses this medicine.

Treating a headache, cold or other minor aches and pains

Try to avoid taking medicines containing paracetamol (e.g. Panadol®, Panadeine®, Codral®, Tylenol®) to treat minor aches and pains. Ask your pharmacist to suggest an alternative medicine.

Driving or using machines

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

Glivec may cause dizziness, light-headedness or drowsiness in some people.

Wear sun protection when outdoors

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use sunlamps or tanning beds.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

There are no known interactions of Glivec with alcohol.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it

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 windowsills

Keep it where young children cannot reach it.

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
Stomach and intestine problems: • pain or burning sensation in upper tummy area and/or chest (heartburn), feeling sick, vomiting, feeling of fullness and bloating, black-coloured	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
stool (signs of stomach ulcer). **Skin problems:** • skin rash with flaking or peeling (exfoliative dermatitis). • blisters on skin (signs of pemphigus). • painful and/or blistering skin areas • decreased or increased skin sensitivity. • changes in skin colour. • red bumps or white-headed pimples around the roots of the hair, possibly with pain, itching or burning feeling (signs of swelling of the hair follicles, also called folliculitis). • painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin, also called panniculitis). **General problems:**	

Less serious side effects	What to do
• feeling dizzy or weak. • itching. • unusual hair loss or thinning. • dry mouth, dry skin or dry eye. • hot flushes, chills or night sweats. • severe headache felt as a throbbing pain or pulsing sensation, usually on one side of the head and often with sick feeling, vomiting and sensitivity to light or sound (signs of migraine). • overwhelming urge to move the legs (restless leg syndrome). • burping/belching. • difficulty swallowing. • increased sweating. • brittle nails. • generally feeling unwell. • increase in appetite. • nail discolouration.	

Less serious side effects	What to do
• slowing of growth in children and adolescents. **Ear problems:** • hearing noises (e.g. ringing, humming) in the ears that have no external source (tinnitus). **Eye problems:** • discharge from the eye with itching, redness and swelling (conjunctivitis), watery eyes or having blurred vision. **Blood problems:** • nose bleeds. **Infection problems:** • viral infection such as cold sore. • swelling of the lips. • mouth ulcers. • cough, runny or stuffy nose, feeling of heaviness or pain on pressing the area above the eyes or on the sides of the nose, nasal	

Less serious side effects	What to do
stuffiness, sneezing, sore throat, with or without headache (signs of upper respiratory tract infection). • flu-like symptoms (influenza). • pain or burning feeling while passing urine, increased body temperature, pain in groin or pelvic area, red- or brown-coloured or cloudy urine (signs of urinary tract infection). **Nutrition problems:** • anorexia, weight loss or a change in sense of taste. **Bone and connective tissue problems:** • joint pain with swelling. • pain and swelling of your joints (signs of arthralgia). **Kidney problems:** • Increased frequency of passing urine	

Less serious side effects	What to do
• lower back pain resulting from kidney problems **Muscle problems:** • joint and muscle stiffness. **Nervous system problems:** • difficulty in sleeping (insomnia). • a constant feeling of sadness and loss of interest, which stops you carrying out your normal activities (signs of depression). • a feeling of nervousness and worry along with physical changes such as pounding heart, sweating, trembling, dry mouth (signs of anxiety). • sleepiness/drowsiness/ excessive sleep. • confusion. • memory loss. • trembling or shaky movements (tremor).	

Less serious side effects	What to do
Heart and circulation problems: • numbness of the hands or feet. • reddening and/or swelling on the palms of the hands and soles of the feet with tingling feeling and burning pain. **Reproduction problems:** • breast enlargement (may occur in men or women). • dull pain and/or feeling of heaviness in the testicles or lower tummy area, pain during pee, sexual intercourse or ejaculation, blood in urine (signs of oedema of the testicles). • unable to get or keep an erection (erectile dysfunction). • heavy or irregular menstrual periods.	

Less serious side effects	What to do
• difficulty achieving/ maintaining sexual arousal. • decreased sexual desire. • nipple pain. • slowing of growth in children and adolescents.	

Serious side effects

Serious side effects	What to do
Blood problems: • unexpected bleeding or bruising (when you have not hurt yourself). • feeling light-headed, dizzy or fainting (signs of low blood pressure). • pale skin, feeling tired, difficulty breathing or breathless and having dark urine (signs of low levels of red blood cells).	**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
• numb or cold toes and fingers (signs of Raynaud's syndrome). • muscle weakness and spasms with an abnormal heart rhythm (signs of changes in the amount of potassium in your blood). • bruising. • feeling sick, shortness of breath, irregular heartbeat, cloudy urine, tiredness and/or joint pain with abnormal blood test results (eg. high potassium, uric acid and calcium levels and low phosphorous levels in the blood). • tired, dizziness, shortness of breath, bruises, gum/nose bleeds, minor cuts bleed a lot, feeling confused, sleepiness, seizures, decreased urine, swollen legs, fever (problems with blood clotting).	

Serious side effects	What to do
Stomach and intestine problems: • severe stomach pain, blood in vomit, stool or urine, black stools (signs of gastrointestinal problems) • stomach pain with feeling sick (nausea) • feeling sick (nausea), being sick (vomiting), diarrhoea, or upset stomach or heartburn **General problems:** • rapid weight gain. Glivec may cause your body to keep water (severe fluid retention). • combined widespread severe rash, feeling sick, fever, high level of certain white blood cells or yellow skin or eyes (signs of jaundice) with difficulty breathing, chest pain, severely decreased urine output and feeling thirsty etc.	

Serious side effects	What to do
(signs of a treatment-related allergic reaction). • headache or feeling tired. • swelling such as around your ankles or puffy eyes. • weight gain. **Skin problems:** • rash • rash, red skin with blisters on the lips, eyes, skin or mouth, peeling skin, fever, raised red or purple skin patches, itching, burning feeling (signs of skin problems) • sudden swelling and redness of the skin (signs of a skin infection called cellulitis). **Ear problems:** • difficulty hearing **Eye problems:** • eye pain or worsening eyesight, bleeding in the eyes	

Serious side effects	What to do
Liver problems: • Feeling sick (nausea), with loss of appetite, dark-coloured urine, yellow skin or eyes (signs of liver problems). **Infection problems:** • Signs of infection such as fever, severe chills, sore throat or mouth ulcers. Glivec can reduce the number of white blood cells, so you might get infections more easily. **Bone and connective tissue problems:** • muscle cramps or joint, muscle or bone pain, during Glivec treatment or after you have stopped taking Glivec. • pain in bones or joints (signs of osteonecrosis). **Nervous system problems:**	

Serious side effects	What to do
• severe headache, weakness or paralysis of arms/legs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system problems such as bleeding or swelling in skull/brain). **Heart problems:** • chest pain, irregular heart rhythm (signs of heart problems). **Excretory system problems:** • feeling sick (nausea) with diarrhoea and vomiting, stomach pain or fever (signs of bowel problems). **Muscle problems:** • muscle spasms with a fever, red-brown urine, pain or weakness in your muscles.	

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 Glivec contains

Active ingredient **(main ingredient)**	imatinib
Other ingredients **(inactive ingredients)**	Cellulose-microcrystalline Crospovidone Hypromellose Silica colloidal anhydrous

	Magnesium stearate Iron oxide yellow CI77492 (E172) Iron oxide red CI77491 (E172) Macrogol 4000 Talc
Potential allergens	Glivec does not contain sucrose, lactose, tartrazine, azo dyes, or any animal products.

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

What Glivec looks like

Glivec 100 mg tablet is a round, very dark yellow to brownish orange tablet with NVR on one side and SA and score-line on the other side; packs of 60 tablets. AUST R 94216.

Glivec 400 mg tablet is an oval, very dark yellow to brownish orange tablet with 400 on one side and score on the other side and SL on each side of the score; packs of 30 tablets. AUST R 94217.

Who distributes Glivec

Glivec 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

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