

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 Gilmat?

Gilmat contains the active ingredient imatinib mesilate. Gilmat is used to treat adults and children/adolescents who have chronic myeloid leukaemia (CML) and acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL). Gilmat is also used to treat adults for: myelodysplastic /myeloproliferative diseases (MDS/MPD); Hypereosinophilic syndrome (HES) and or chronic eosinophilic leukaemia (CEL); gastro-intestinal stromal tumours (GIST); dermatofibrosarcoma protuberans (DFSP).

For more information, see Section [1. Why am I using Gilmat?](#) in the full CMI.

2. What should I know before I use Gilmat?

Do not use if you have ever had an allergic reaction to imatinib 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 Gilmat?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Gilmat 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 Gilmat?

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

More instructions can be found in Section [4. How do I use Gilmat?](#) in the full CMI.

5. What should I know while using Gilmat?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using Gilmat. <ul style="list-style-type: none">– Make sure you follow your doctor's instructions carefully and keep all appointments.– Make sure you use a method of contraception to prevent pregnancy during treatment with Gilmat and for 15 days after ending treatment.– Tell your doctor immediately if you become pregnant while you are taking this medicine.
Things you should not do	<ul style="list-style-type: none">– 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.
Driving or using machines	<ul style="list-style-type: none">– Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Gilmat affects you.
Looking after your medicine	Store in the original package below 25°C and protect from moisture. Keep out of the reach of children.

For more information, see Section [5. What should I know while using Gilmat?](#) in the full CMI.

6. Are there any side effects?

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

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.

Gilmat®

Active ingredient(s): *imatinib mesilate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Gilmat?

Gilmat contains the active ingredient imatinib mesilate.

Gilmat is used to treat adults and children/adolescents who have chronic myeloid leukaemia (CML) and acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL).

CML and ALL are types of leukaemia in which an abnormal chromosome produces an enzyme that leads to uncontrolled growth of white blood cells. Gilmat kills the abnormal cells while leaving normal cells alone.

Gilmat 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.

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.

Gilmat works by slowing the growth of abnormal cells. Gilmat 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.

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

There is not enough information to recommend the use of Gilmat in children under 3 years of age for most uses. For use in CML, there is no experience with the use of Gilmat in children below 2 years of age. For acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL), there is no experience with the use of Gilmat in children below 1 year of age.

2. What should I know before I use Gilmat?

Warnings

Do not use Gilmat if:

you are allergic to Gilmat, or any of the 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.

Always check the ingredients to make sure you can use this medicine.

Do not take Gilmat 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.

Check with your doctor if you:

have any other medical conditions or procedures:

- kidney or liver problems
- problems with your heart
- you have had your thyroid gland removed
- hepatitis B infection. As during treatment with Gilmat, hepatitis B (an infection of the liver) may become active again.

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

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 discuss with you the risks and benefits involved.

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. Because this medicine could affect your baby, breastfeeding is not recommended.

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 and Gilmat may interfere with each other. These include many medicines that are eliminated from the body through the liver:

- 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. A patient, who was taking paracetamol regularly for fever, died of acute liver failure. Although the cause is currently unknown, special caution should be exercised when using paracetamol and Gilmat.
- 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

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.

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

4. How do I use Gilmat?

How much to take

- For CML, the usual dose for an adult is 400 to 600 mg each day and the maximum dose is 800 mg each day. The dose depends on what stage of CML you have.
- For Ph-positive ALL the usual dose is 600 mg each day.
- For children treated with CML and Ph-positive ALL, the dose depends on the size of the child.
- For MDS/MPD, the starting dose is 400 mg.
- For HES/CEL, the usual starting dose is 400 mg. For some patients the starting dose may be 100 mg.
- For GIST, the usual dose is 400 mg or 600 mg each day.
- For DFSP, the starting dose is 800 mg per day.

Daily dose of 400 mg should be taken as one tablet of 400 mg once a day.

Daily dose of 600 mg should be taken as either:

- six tablets of 100 mg or
- one tablet of 400 mg plus half a 400 mg tablet

once a day.

Daily dose of 800 mg should be taken as 400 mg twice a day, in the morning and in the evening.

Your doctor may direct you to take a higher or lower dose, or stop treatment if needed depending on your response to Gilmat.

Follow the instructions provided and use Gilmat until your doctor tells you to stop.

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.

When to take Gilmat

Gilmat 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.

How to take Gilmat

Take the medicine with a large glass of water and food.

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

If you are unable to swallow the tablets:

- Put the required tablet(s) in a glass of water or apple juice (approximately 50 mL for a 100 mg tablet and 200 mL for a 400 mg tablet).
- Stir with a spoon to completely disintegrate the tablet(s).
- Immediately drink the whole contents of the glass.

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

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

How long to take Gilmat

Continue taking Gilmat 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 Gilmat

Take the missed dose as soon as you remember, then continue with your normal schedule.

Do not take a double dose to make up for the dose 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 use too much Gilmat

If you think that you have used too much Gilmat, 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.

Keep the telephone numbers for these places handy.

5. What should I know while using Gilmat?

Things you should do

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, weight checks and urine tests can also find side effects before they become serious.

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

Make sure you use a method of contraception to prevent pregnancy during treatment with Gilmat and for 15 days after ending treatment. 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 Gilmat.

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

Things you should 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

Avoid drinking grapefruit juice while you are being treated with Gilmat.

Grapefruit juice may interact with Gilmat and affect how your body uses this medicine.

If you need to take something to treat a headache, cold or other minor aches and pains, try to avoid taking medicines containing paracetamol (e.g. Panadol®, Panadeine®, Codral®, Tylenol®). Ask your pharmacist to suggest an alternative medicine.

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.

Driving or using machines

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

This medicine may cause dizziness, light-headedness or drowsiness 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.

Looking after your medicine

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

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

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.

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

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
<ul style="list-style-type: none"> • swelling of fingers, eyelids, face or lower legs due to fluid build up (see your doctor immediately if fluid build up is severe) • indigestion, upset stomach, wind, feeling of bloating • nausea (feeling sick) or vomiting • diarrhoea • constipation • dry mouth • swelling, aching, cramping or stiffness in joints or muscles • musculoskeletal pain after stopping Gilmat (including muscle pain, limb pain, joint pain, bone pain and back pain) • pain in the bones or along veins • headache • dizziness, light-headedness or vertigo (spinning sensation) • tiredness, weakness, feeling generally unwell • numbness, coldness or tingling in fingers and toes • difficulty sleeping, feeling anxious, depressed, confused or forgetful • change in sense of taste • rash, eczema, itching, dry skin, darkening or lightening of skin • symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which happens more quickly than normal • painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin, also called panniculitis) • irritated, red, runny or itchy eyes, blurred vision • ringing in the ears • changes in appetite and weight • hair loss • sweating during the night • throat pain • cough or cold symptoms • loss of interest in sex, problems with sexual function • breast enlargement, nipple pain, painful periods • reddening and/or swelling on the palms of the hands and soles of the feet which may be 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • severe allergic reaction that can result in difficulty breathing, dizziness. • rapid weight gain, swelling of the extremities (calves, ankles), generalised swelling such as swelling of the face (signs of water retention) • weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, swollen glands, sore throat or mouth ulcers (signs of low level of blood cells) • pale skin, tiredness, breathlessness, dark urine (signs of break down of red blood cells). • pain and having difficulty walking • cough, difficult or painful breathing, wheezing, pain in chest when breathing (signs of lung infections/disorders). • muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood). • muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles (signs of muscle disorders) • pain in bones or joints (signs of osteonecrosis) • severe abdominal pain, vomiting blood, black or bloody stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain (signs of gastrointestinal disorders) • thirst, weight loss and severely decreased urine output (signs of low intake of drinks/fluids) • nosebleeds or any other unusual bleeding • vision impairment, blurred vision, blood in eye • nausea, loss of appetite, darkcoloured urine or yellowing of your skin or eyes (signs of liver disorders). • Changes in urine or blood in urine, pain in the kidney area, tiredness, loss of appetite, nausea/vomiting, lack of concentration, headache, cramping, itching (signs of kidney disorders) • nausea, diarrhoea, vomiting, abdominal pain, fever (signs of inflammatory bowel disease). 	<p>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.</p>

peeling, fever, red raised or purple skin patches, itching, burning, pustular eruption (signs of skin disorder).

- severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands, stomach pain or aching joints and muscles
- inflammation of the skin caused by an infection (sign of cellulitis)
- blood in the urine
- severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system disorder such as bleeding or swelling in the brain)
- seizures (fits)
- swelling and pain in one part of the body (signs of clots in blood vessels)
- crushing chest pain, fever, tiredness, irregular heart beat (signs of heart disorders such as heart attack, angina).
- pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding, (signs of gynaecological disorder)
- nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory (such as high potassium, uric acid, and phosphorous levels and low calcium levels in the blood)
- severe headache, dizziness, blurred vision (signs of increased pressure inside skull)
- 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).
- Fatigue, dizziness, shortness of breath, bruises, gum/nose bleeds, minor cuts that bleed a lot, confusion, sleepiness, seizures, decreased urine, swollen legs, fever (potential signs of thrombotic microangiopathy).

Other side effects not listed here may occur in some people. Some of these side effects can only be found by laboratory testing.

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 Gilmat contains

Active ingredient (main ingredient)	imatinib 100 mg or 400 mg
Other ingredients (inactive ingredients)	magnesium stearate Opadry white 03F58763 (ARTG ID: 111313)
Potential allergens	

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

What Gilmat looks like

Gilmat 100 mg film—coated tablet is a white to off—white coloured, round, bevel edged scored tablets debossed with H on one side and 19 on the other side, 1 and 9 separated by a score line.

Blister packs of 60, 90 and 120 (Aust R 281036)

HDPE bottles of 60 and 90 (Aust R 264718)

Gilmat 400mg film—coated tablet is a white to off—white coloured, capsule shaped, bevel edged scored, filmcoated tablets debossed with H on one side and 20 on the other side, 2 and 0 separated by a score line.

Blister packs of 30 (Aust R 264758)

HDPE bottles of 30 (Aust R 264778)

Who distributes Gilmat

Pharmacor Pty Ltd
Suite 803, Tower A, The Zenith,
821 Pacific Highway,
Chatswood NSW 2067
Australia

Web: www.pharmacor.com.au

Phone: 1300 138 805

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

This leaflet was prepared in November 2022.