

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **GLEEVEC®**

Imatinib Mesylate Tablets

Read this carefully before you start taking **GLEEVEC®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **GLEEVEC**.

Serious Warnings and Precautions

Take GLEEVEC only under the care of a doctor who knows how to use anti-cancer drugs. They should be trained in how to treat solid tumours or blood cancers.

GLEEVEC can cause serious side effects,

- **Heart disease or problems** where your heart is unable to pump enough blood to meet the body's needs. These include:
 - **Left ventricular dysfunction**
 - **Congestive heart failure**
 - **Cardiogenic shock**
- **Water retention:** a build-up of water in your body
- **Side effects caused by water retention.** These include:
 - **Pleural effusion:** fluid around the lungs
 - **Pulmonary edema:** fluid in the air space of the lungs
 - **Pericardial effusion:** fluid around the heart
 - **Ascites:** fluid in the abdomen
- **Rhabdomyolysis:** a rapid breakdown of muscle. It may lead to sudden kidney failure.
- **Severe bleeding**
- **Liver disorder, jaundice, toxicity or failure.** In some patients, liver failure has led to death.
- **Gastrointestinal perforation:** a hole in the wall of your stomach, small or large bowel. In some patients, it has led to death.

What is GLEEVEC used for?

GLEEVEC is used to treat several solid tumour or blood cancer conditions in adults. GLEEVEC can also be used in children for one blood cancer condition.

Ask your doctor if you are not sure why GLEEVEC has been prescribed for you.

How does GLEEVEC work?

GLEEVEC helps slow down or stop the growth of cancer cells in your body.

What are the ingredients in GLEEVEC?

Medicinal ingredient: Imatinib mesylate

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, ferric oxide (red), ferric oxide (yellow), hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, and talc.

GLEEVEC comes in the following dosage forms:

Tablets: 100 mg, 400 mg

Do not use GLEEVEC if:

- You are allergic to imatinib or any of the non-medicinal ingredients found in GLEEVEC.
- You are breast-feeding. You must stop breast-feeding before taking GLEEVEC and 15 days after the last dose. It can get into breast milk and harm your baby. Talk to your healthcare professional about the best way to feed your baby during treatment with GLEEVEC.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take GLEEVEC. Talk about any health conditions or problems you may have, including if you:

- have heart problems;
- have liver problems;
- have kidney problems;
- have stomach problems;
- have bowel problems;
- have bleeding problems;
- have bleeding from your stomach, small bowel, or large bowel;
- have your thyroid removed and take a thyroid hormone such as levothyroxine. This may cause your thyroid to be underactive during treatment with GLEEVEC. Your doctor should closely monitor your blood thyroid hormone levels during treatment;
- have ever had or you think you currently have a hepatitis B virus infection (a viral infection of the liver). This is because during treatment with GLEEVEC, hepatitis B may become active again, which can be fatal in some cases. Your doctor will check for signs of this infection before and during treatment with GLEEVEC.

Other warnings you should know about:

Tumour Lysis Syndrome:

- Treatment with GLEEVEC can cause a serious side effect called Tumour Lysis Syndrome (TLS). TLS usually occurs after treatment of a large or fast-growing cancer. As tumour cells die, they release their contents. This leads to high levels of certain chemicals (potassium, uric acid, phosphorous) and low levels of calcium in the blood. High or low levels of these chemicals can cause damage to your organs and may lead to death.
- Some people are at baseline risk of TLS. If your doctor determines this is true for you, prior to starting GLEEVEC, they might give you treatments that may decrease the risk of TLS.

Osteonecrosis:

- Osteonecrosis has been uncommonly reported in adults and children treated with GLEEVEC. Osteonecrosis is the death of bone tissues due to lack of blood supply. This leads to tiny breaks in the bone and causes the bone to collapse.
- This condition may affect different areas of your body but most commonly affects the hip. Other areas that may be affected include: femur shaft (straight part of your thighbone), shinbone, heel bone, jaw and finger. Talk to your healthcare professional right away if you experience bone or joint pain in any of these areas.
- In serious cases, your doctor will determine if you need to stop taking GLEEVEC and/or undergo surgical treatments.

Female patients:

Pregnancy and birth control

- If you are pregnant or plan to become pregnant, there are specific risks you should discuss with your healthcare professional.
- GLEEVEC can harm your unborn baby. Your healthcare professional may ask you to take a pregnancy test before taking GLEEVEC.
- While taking GLEEVEC, you should use highly effective birth control. Continue taking birth control for 15 days after ending treatment.
- If you become pregnant while taking GLEEVEC, or think you might be, tell your healthcare professional right away.

Male patients:

If you are trying to have a child, talk to your healthcare professional. Your healthcare professional may advise you not to start treatment with GLEEVEC while you are trying to have a child. If you are already taking GLEEVEC, your healthcare professional may advise you to stop taking GLEEVEC before you try to have a child.

Fertility in male patients:

Treatment with GLEEVEC may affect your ability to have children. Talk to your healthcare professional if this is a concern for you.

Driving and using machines:

GLEEVEC can cause vision problems, dizziness or fatigue. Before doing tasks which require special attention, wait until you are feeling well again.

Monitoring and testing:

You will have regular visits with your healthcare professional during treatment with GLEEVEC to monitor your health. They will:

- Weigh you regularly.
- Measure growth in growing children. While taking GLEEVEC, children may grow more slowly.
- Do blood tests and/or urine tests to check how well your kidneys are working. This will be done before you start taking GLEEVEC and during your treatment.
- Do blood tests to check your blood cell counts. This will be done every week for the first month, every 2 weeks for the second month and regularly thereafter (as needed).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with GLEEVEC:

- some medicines used to treat fungal infections, like ketoconazole, itraconazole
- some medicines used to treat bacterial infections, like erythromycin, or clarithromycin
- some medicines used to treat epilepsy, like carbamazepine, oxcarbazepine, phenobarbital, phenytoin, fosphenytoin, or primidone
- some medicines used to treat high cholesterol like simvastatin
- some medicines used to treat mental health disorders like pimozide
- some medicines used to treat high blood pressure or heart disorders. This includes metoprolol or a group of medicines called calcium channel blockers
- rifampicin a medicine used to treat tuberculosis (TB)
- St. John's Wort (*Hypericum perforatum*), a herbal product used to treat depression and other conditions
- dexamethasone, a medicine to treat inflammation
- cyclosporine, a medicine that keeps the immune system from rejecting a new organ after a transplant
- acetaminophen, a medicine used to reduce pain or fever — acetaminophen is also included in many cold and flu remedies, so check the label
- warfarin, a medicine used to treat or prevent blood clots
- levothyroxine, if you had your thyroid removed
- grapefruit juice. Do NOT drink grapefruit juice at any time while you are on GLEEVEC.

If you are already taking GLEEVEC, tell your healthcare professional if you are prescribed a new medicine.

How to take GLEEVEC:

- Take GLEEVEC exactly as your healthcare professional tells you. They will tell you exactly how many tablet(s) to take per day, and how often to take them.
- Take by mouth with food and a large glass of water.

You can take GLEEVEC in one of these two ways:

1. Swallow GLEEVEC:
 - a) Whole with a large glass of water.
 - b) If the 400 mg tablet is too large to swallow whole:
 - Break it in two pieces
 - Swallow each piece with water, one after the other
2. If you **cannot swallow** a 400 mg tablet broken in two or a 100 mg tablet:

Place the tablet in a glass with water or apple juice.

100 mg tablet: use 50 mL or one-quarter cup

400 mg tablet: use 200 mL or a little less than 1 cup

 - Stir with a spoon to completely dissolve the tablet
 - Drink the whole drink right away
 - Rinse the glass with a little more water or juice and drink that too
 - No trace of the dissolved tablet should be left behind in the glass

Usual dose:

Your healthcare professional will decide the best dosage for you. Your dose depends on if you are an

adult or a child, and on your medical condition.

If your daily dose is:

- **600 mg or less:** take once a day, around the same time every day.
- **800 mg:** take twice a day. A 400 mg tablet in the morning and another 400 mg tablet in the evening. To reduce how much iron you get, **use only** the 400 mg tablets to make up your dose.

Your healthcare professional will regularly monitor your condition. They may change your dose depending on how well GLEEVEC is working.

Overdose:

If you think you, or a person you are caring for, have taken too much GLEEVEC, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose OR threw up after taking the last dose, skip the missed dose. Take your next dose at the usual time.

What are possible side effects from using GLEEVEC?

These are not all the possible side effects you may have when taking GLEEVEC. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- | | |
|--|--|
| • weight loss, no appetite, change in taste, dry mouth, sores in mouth | • night sweats, red in the face or other areas of the skin |
| • heartburn, indigestion | • unusual hair loss or thinning |
| • constipation, gas, feel bloated | • muscle tension, cramps, pain |
| • headache, dizziness | • bone pain |
| • difficulty sleeping, drowsiness | • joint pain and swelling |
| • weakness, feeling tired | • tingling, pain, or numbness in hands, feet, legs |
| • nosebleeds | • cough |
| • skin dry, itchy or less sensitive to touch | • increased tears in the eyes, dry eyes. |
| • skin more sensitive to sun | |

If any of these affects you severely, tell your healthcare professional.

GLEEVEC can also cause abnormal blood test results.

Children who take GLEEVEC may have the following side effects more often than adults:

- Low blood levels of calcium, sugar, phosphates, albumin protein and sodium
- High blood levels of sugar

Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Water retention: rapid weight gain, swelling of your hands, ankles, feet, face, or eyelids, or your whole body.		√	
Decreased Platelets: bruising, bleeding, fatigue and weakness.		√	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms.		√	
Anemia (Decreased red blood cells): fatigue, loss of energy, weakness, shortness of breath.		√	
Musculoskeletal pain after discontinuing treatment with GLEEVEC: muscle pain, limb pain, joint pain and bone pain.		√	
COMMON			
Pleural effusion (fluid around the lungs): chest pain. Difficult or painful breathing, cough.			√
Pulmonary edema (fluid in the air spaces of the lungs): difficult breathing that is worse when you lie down. Cough up blood or blood-tinged froth.			√
Pericardial effusion (fluid around the heart): chest pain that feels better when you sit up rather than lie down. Feel light-headed or pass out. Irregular, fast, or forceful heartbeat. Difficult or painful breathing, cough.			√
Ascites (fluid in the abdomen): feeling of fullness, abdominal pain, shortness of breath.			√
Bleeding or swelling in the brain: severe headache. Weak or cannot move arms, legs or face. Difficulty talking, fainting or passing out. Dizziness, blurred vision, seizure (fit).			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Pneumonia (infection in the lungs): shortness of breath. Difficult and painful breathing, cough, wheezing, or fever.			√
Shortness of Breath	√		
Chest Pain		√	
Inflammatory bowel disease: nausea, vomiting, diarrhea, abdominal pain, fever.		√	
Liver disorder, jaundice, toxicity, or failure: yellow skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.			√
Vomiting	√		
Diarrhea	√		
Nausea	√		
Pain in the abdomen	√		
Fever	√		
Less urine, urinate less often.		√	
Eye Infection (conjunctivitis): itchy, red eyes with discharge, and swelling.		√	
Swelling around the eyes or in the eyelids.		√	
UNCOMMON			
Bleeding in the stomach or bowels: severe abdominal pain, vomit blood, black or bloody bowel movement, swelling of the abdomen. Feel dizzy or weak, loss of consciousness. Shortness of breath.			√
Gastrointestinal perforation (a hole in the wall of your stomach or bowels): severe abdominal pain, nausea, vomiting, chills or fever.			√
Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell.		√	
Interstitial lung disease (diseases that inflame or scar lung tissue):			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
shortness of breath, tiredness, dry cough.			
Acute respiratory failure: sudden worsening of shortness of breath, bluish color on skin, lips, and fingernails, irregular heartbeats, feel sleepy, loss of consciousness.			√
Low Blood Pressure: dizziness, fainting, light-headedness.		√	
Fainting or passing out		√	
Difficulty hearing		√	
Blood in urine		√	
Left ventricular dysfunction, Congestive heart failure (a weakness of the heart): tiredness, swollen ankles, shortness of breath especially when lying down.			√
Heart attack (blood flow stops to part of the heart): sudden chest pain or pressure or discomfort, feeling faint, shortness of breath, possibly irregular heartbeat.			√
Cardiogenic shock (heart is not able unable to pump enough blood to the organs of the body): breathe fast, fast heartbeat, loss of consciousness, sweating, pale skin, cold hands or feet.			√
Angina (not enough oxygen to the heart muscle): chest pain or pressure, usually coming during exercise or physical stress and relieved by rest.			√
Raynaud's syndrome: fingers and toes feel numb and cold in response to cold temperatures or stress.		√	
Cellulitis (infection under the skin): red, hot, painful and swollen area.		√	
Palmar-plantar erythrodysesthesia syndrome: red or swollen palms of the hands and soles of the feet. You might		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
feel a tingling or burning pain as well.			
Tumour lysis syndrome: nausea, shortness of breath, irregular heartbeat, cloudy urine, tiredness, or pain in joints.			√
Osteonecrosis (break down and collapse of bone tissue): pain in bone or joints.		√	
Panniculitis (inflammation of fatty tissue under the skin): painful red lumps on the skin, skin pain, skin reddening.		√	
RARE			
Eye Problems: blood in eye, trouble seeing, blurred vision.		√	
Pulmonary fibrosis (scarring of the lung tissues): shortness of breath, tiredness, dry cough.			√
Seizure		√	
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center. Possibly swollen lips. Mild itching or burning.			√
Stevens Johnson syndrome, Toxic epidermal necrolysis (severe skin reaction): rash, red skin, red or purple skin patches possibly with blister or crust in the center, pus-filled rash, peeling skin, blisters on the lips, eyes, skin or in the mouth, itching, burning, flu-like feeling, fever.			√
Breakdown of red blood cells: pale skin, feeling tired or out of breath, dark urine.		√	
Pemphigus: blisters on skin or mucous membranes.		√	
UNKNOWN FREQUENCY			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reactions: itch, rash, hives, swelling of the lips, tongue or throat, difficulty swallowing or breathing.			√
Drug reaction with eosinophilia and systemic symptoms (DRESS) (severe reaction to a medicine. Your skin and one or more of the organs in your body are involved. You may only have some of the side effects that are listed here): fever, severe rash, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinate less often, less urine.			√
Rhabdomyolysis (a rapid breakdown of muscle): unexplained muscle pain, tenderness or weakness. Dark brown urine.		√	
Blood clot in blood vessel: swelling, redness and pain in one part of the body.		√	
Gynecological disorder (problem in woman's reproductive system): pain in lower abdomen or unexpected blood from the vagina or both.		√	
Chronic Kidney Impairment (reduced kidney function).		√	
Hepatitis B virus reactivation (an active viral infection of the liver): Fever, skin rash, joint pain and inflammation as well as tiredness, loss of appetite, nausea, jaundice (yellowing of the skin or whites of eyes), pain in the upper right abdomen, pale stools and dark urine.		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Pseudoporphyria (painful blisters on sun-exposed skin; sunburn-type rash).		√	
Thrombotic Microangiopathies (problems related to blood clots in small blood vessels): bleeding, bruising, weakness, confusion, fever, nausea, vomiting and diarrhea and acute kidney failure.			√

These are not all the possible side effects you may feel when taking GLEEVEC. If you experience any side effects not listed here, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store the medication package at room temperature (100 mg: 15°C to 30°C; 400 mg: 15°C to 25°C).
- Keep tablets in their original package.
- Protect the tablets from moist air. Make sure the tablets do not get wet.
- Use tablets before the expiry date on the box. Do NOT use tablets after that date.
- If a package is damaged or shows signs of tampering, do NOT use the tablets.
- Keep out of sight and reach of children.

If you want more information about GLEEVEC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this

Patient Medication Information by visiting the Health Canada website:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website: www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised August 31, 2022

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