

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### PrIMATINIB

#### Imatinib Mesylate Tablets

Read this carefully before you start taking **IMATINIB** 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 **IMATINIB**.

#### Serious Warnings and Precautions

Take IMATINIB 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.

**IMATINIB** 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 IMATINIB used for?

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

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

### **How does IMATINIB work?**

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

### **What are the ingredients in IMATINIB?**

Medicinal ingredients: imatinib mesylate

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, ferric oxide red, ferric oxide yellow, hydroxypropyl cellulose, hypromellose, magnesium stearate and polyethylene glycol.

### **IMATINIB comes in the following dosage forms:**

Tablets: 100 mg, 400 mg

### **Do not use IMATINIB if:**

- You are allergic to imatinib or any of the non-medicinal ingredients found in IMATINIB.
- You are breast-feeding. You must stop breast-feeding before taking IMATINIB 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 IMATINIB.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IMATINIB. 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 IMATINIB. 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 IMATINIB, 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 IMATINIB.

**Other warnings you should know about:**

**Tumour Lysis Syndrome:**

- Treatment with IMATINIB 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 IMATINIB, they might give you treatments that may decrease the risk of TLS.

**Osteonecrosis:**

- Osteonecrosis has been uncommonly reported in adults and children treated with imatinib mesylate. 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 IMATINIB 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.
- IMATINIB can harm your unborn baby. Your healthcare professional may ask you to take a pregnancy test before taking IMATINIB.
- While taking IMATINIB, you should use highly effective birth control. Continue taking birth control for 15 days after ending treatment.
- If you become pregnant while taking IMATINIB, 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 IMATINIB while you are trying to have a child. If you are already taking IMATINIB, your healthcare professional may advise you to stop taking IMATINIB before you try to have a child.

**Fertility in male patients:**

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

**Driving and using machines:**

IMATINIB 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 IMATINIB to monitor your health. They will:

- Weigh you regularly.
- Measure growth in growing children. While taking IMATINIB, 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 IMATINIB 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 IMATINIB:**

- 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 IMATINIB

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

#### How to take IMATINIB:

- Take IMATINIB 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 IMATINIB in one of these two ways:

1. Swallow IMATINIB:

- 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 IMATINIB is working.

## Overdose:

If you think you, or a person you are caring for, have taken too much IMATINIB, 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 IMATINIB?

These are not all the possible side effects you may have when taking IMATINIB. 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
- heartburn, indigestion
- constipation, gas, feel bloated
- headache, dizziness
- difficulty sleeping, drowsiness
- weakness, feeling tired
- nosebleeds
- skin dry, itchy or less sensitive to touch
- skin more sensitive to sun
- night sweats, red in the face or other areas of the skin
- unusual hair loss or thinning
- muscle tension, cramps, pain
- bone pain
- joint pain and swelling
- tingling, pain, or numbness in hands, feet, legs
- cough
- increased tears in the eyes, dry eyes.

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

IMATINIB can also cause abnormal blood test results.

Children who take IMATINIB 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.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON</b>			
<b>Water retention:</b> rapid weight gain, swelling of your hands, ankles, feet, face, or eyelids, or your whole body.		√	
<b>Decreased Platelets:</b> bruising, bleeding, fatigue and weakness.		√	
<b>Decreased White Blood Cells:</b> infections, fatigue, fever, aches, pains, and flu- like symptoms.		√	
<b>Anemia</b> (Decreased red blood cells): fatigue, loss of energy, weakness, shortness of breath.		√	
<b>Musculoskeletal pain after discontinuing treatment with IMATINIB:</b> muscle pain, limb pain, joint pain and bone pain.		√	
<b>COMMON</b>			
<b>Pleural effusion</b> (fluid around the lungs): chest pain. Difficult or painful breathing, cough.			√
<b>Pulmonary edema</b> (fluid in the air spaces of the lungs): difficult breathing that is worse when you lie down. Cough up blood or blood- tinged froth.			√
<b>Pericardial effusion</b> (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,			√

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Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or forceful heartbeat. Difficult or painful breathing, cough.			
<b>Ascites</b> (fluid in the abdomen): feeling of fullness, abdominal pain, shortness of breath.			√
<b>Bleeding or swelling in the brain:</b> severe headache. Weak or cannot move arms, legs or face. Difficulty talking, fainting or passing out. Dizziness, blurred vision, seizure (fit).			√
<b>Pneumonia</b> (infection in the lungs): shortness of breath. Difficult and painful breathing, cough, wheezing, or fever.			√
<b>Shortness of Breath</b>	√		
<b>Chest Pain</b>		√	
<b>Inflammatory bowel disease:</b> nausea, vomiting, diarrhea, abdominal pain, fever.		√	
<b>Liver disorder, jaundice, toxicity, or failure:</b> 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.		√	
<b>Eye Infection</b> (conjunctivitis): itchy, red eyes with discharge, and swelling.		√	
Swelling around the eyes or in the eyelids.		√	
<b>UNCOMMON</b>			
<b>Bleeding in the stomach or bowels:</b> severe abdominal pain, vomit blood, black or bloody bowel movement, swelling of the abdomen. Feel dizzy or			√



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	
weak, loss of consciousness. Shortness of breath.			
<b>Gastrointestinal perforation</b> (a hole in the wall of your stomach or bowels): severe abdominal pain, nausea, vomiting, chills or fever.			√
<b>Decreased or increased levels of potassium in the blood:</b> irregular heartbeats, muscle weakness and generally feeling unwell.		√	
<b>Interstitial lung disease</b> (diseases that inflame or scar lung tissue): shortness of breath, tiredness, dry cough.			√
<b>Acute respiratory failure:</b> sudden worsening of shortness of breath, bluish color on skin, lips, and fingernails, irregular heartbeats, feel sleepy, loss of consciousness.			√
<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness.		√	
Fainting or passing out		√	
Difficulty hearing		√	
Blood in urine		√	
<b>Left ventricular dysfunction, Congestive heart failure</b> (a weakness of the heart): tiredness, swollen ankles, shortness of breath especially when lying down.			√
<b>Heart attack</b> (blood flow stops to part of the heart): sudden chest pain or pressure or discomfort, feeling faint, shortness of breath, possibly irregular heartbeat.			√
<b>Cardiogenic shock</b> (heart is not able to pump enough blood to the organs of the body): breathe fast, fast heartbeat, loss of consciousness, sweating, pale skin, cold hands or feet.			√
<b>Angina</b> (not enough oxygen to the heart muscle): chest pain or pressure, usually			√

Serious side effects and what to do about them			
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	Only if severe	In all cases	
coming during exercise or physical stress and relieved by rest.			
<b>Raynaud's syndrome:</b> fingers and toes feel numb and cold in response to cold temperatures or stress.		√	
<b>Cellulitis</b> (infection under the skin): red, hot, painful and swollen area.		√	
<b>Palmar-plantar erythrodysesthesia syndrome:</b> red or swollen palms of the hands and soles of the feet. You might feel a tingling or burning pain as well.		√	
<b>Tumor lysis syndrome</b> nausea, shortness of breath, irregular heartbeat, cloudy urine, tiredness, or pain in joints.			√
<b>Osteonecrosis</b> (break down and collapse of bone tissue): pain in bone or joints.		√	
<b>Panniculitis</b> (inflammation of fatty tissue under the skin): painful red lumps on the skin, skin pain, skin reddening.		√	
<b>RARE</b>			
<b>Eye Problems:</b> blood in eye, trouble seeing, blurred vision.		√	
<b>Pulmonary fibrosis</b> (scarring of the lung tissues): shortness of breath, tiredness, dry cough.			√
<b>Seizure</b>		√	
<b>Erythema multiforme</b> (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.			√
<b>Stevens Johnson syndrome, Toxic epidermal necrolysis</b> (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			√

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	
the mouth, itching, burning, flu-like feeling, fever.			
<b>Breakdown of red blood cells:</b> pale skin, feeling tired or out of breath, dark urine.		√	
<b>Pemphigus:</b> blisters on skin or mucous membranes.		√	
<b>UNKNOWN FREQUENCY</b>			
<b>Allergic reactions:</b> itch, rash, hives, swelling of the lips, tongue or throat, difficulty swallowing or breathing.			√
<b>Drug reaction with eosinophilia and systemic symptoms (DRESS)</b> (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.			√
<b>Rhabdomyolysis</b> (a rapid breakdown of muscle): unexplained muscle pain, tenderness or weakness. Dark brown urine.		√	
<b>Blood clot in blood vessel:</b> swelling, redness and pain in one part of the body.		√	
<b>Gynecological disorder</b> (problem in woman's reproductive system): pain in lower abdomen or unexpected blood from the vagina or both.		√	
<b>Chronic Kidney Impairment</b> (reduced kidney function).		√	
<b>Hepatitis B virus reactivation</b> (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		√	

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	
of eyes), pain in the upper right abdomen, pale stools and dark urine.			
<b>Pseudoporphyria</b> (painful blisters on sun-exposed skin; sunburn-type rash).		√	
<b>Thrombotic Microangiopathies</b> (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 IMATINIB. If you experience any side effects not listed here, tell your healthcare professional.

<p><b>Reporting Side Effects</b></p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> <li>• Visiting the Web page on Adverse Reaction Reporting (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>) for information on how to report online, by mail or by fax; or</li> <li>• Calling toll-free at 1-866-234-2345.</li> </ul> <p><i>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.</i></p>
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**Storage:**

- Keep out of reach and sight of children.
- Store IMATINIB at room temperature (15°C to 30°C).
- Store IMATINIB in the original package.
- Do not use IMATINIB after the expiry date shown on the box.
- Do not use any IMATINIB pack that is damaged or shows signs of tampering.

**If you want more information about IMATINIB:**

- 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.sivem.ca](http://www.sivem.ca), or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC, 4705 Dobrin Street, Saint-Laurent, Quebec, Canada, H4R 2P7.

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