

**PART III: CONSUMER INFORMATION****Pr BOSULIF®  
(bosutinib tablets)**

This leaflet is part III of a three-part "Product Monograph" published when BOSULIF was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BOSULIF. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

BOSULIF is used to treat adults:

- who have a new diagnosis of a white blood cell cancer called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in a chronic phase or
- who have Ph+ CML in a chronic, accelerated, or blast phase (the blood cancer grows faster in accelerated or blast than in chronic phase) and for whom previous medicines to treat Ph+ CML have either not worked or not been suitable.

A qualified healthcare professional experienced in the used of anticancer therapies and in the treatment of CML should prescribe BOSULIF.

BOSULIF has not been studied in children.

**What it does:**

BOSULIF works by slowing down the growth and spread of cancer cells in patients with CML.

**When it should not be used:**

Do not use BOSULIF if you:

- are allergic to BOSULIF or any of the other ingredients of BOSULIF
- have an abnormal electrical signal of the heart (prolongation of QT interval)
- have uncorrectable low levels of potassium or magnesium
- have liver failure

**What the medicinal ingredient is:**

bosutinib

**What the nonmedicinal ingredients are:**

croscarmellose sodium, iron oxide yellow (for 100 mg tablet), iron oxide yellow and iron oxide red (for 400 mg tablet<sup>§</sup>), iron oxide red (for 500 mg tablet), magnesium stearate, microcrystalline cellulose, poloxamer, polyethylene glycol, polyvinyl alcohol, povidone, talc, and titanium dioxide

<sup>§</sup> Not commercially available in Canada

**What dosage forms it comes in:**

Tablets 100 mg, 400 mg<sup>§</sup>, and 500 mg

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions**

Serious side effects with BOSULIF include:

- Drug interactions with inhibitors or inducers of CYP3A4 enzyme. Do NOT use BOSULIF with strong and moderate CYP3A4 inhibitors and inducers (see Serious Drug and Drug-Food Interactions below)
- Gastrointestinal problems (vomiting and diarrhea)
- Liver problems
- Heart problems that may lead to death
- Fluid in the lungs and around the heart (fluid retention)
- Bleeding
- Abnormal electrical signal of the heart

**BEFORE you use BOSULIF talk to your doctor or pharmacist if you:**

- have or have had in the past, a liver, heart, pancreas or kidney problem.
- are pregnant, or plan to become pregnant as BOSULIF could harm an unborn baby. Discuss contraception with your doctor if there is any possibility that you may become pregnant. BOSULIF must not be used during pregnancy.
- are breastfeeding or planning to breast-feed. Do not breast-feed during treatment with BOSULIF as it could harm your baby.
- have gastrointestinal problems (vomiting and diarrhea).
- have ever had or might now have a hepatitis B virus infection (a viral infection of the liver). This is because during treatment with BOSULIF, hepatitis B may become active again which can be fatal in some cases. Your doctor will test for signs of this infection before treatment with BOSULIF and while on treatment if required.

BOSULIF may cause harm to your unborn child. Both male and female patients must use an effective birth control method such as a condom while taking BOSULIF, during interruptions of treatment and for at least 4 weeks after the last dose. This must be done even if you have undergone a successful vasectomy. If you or your partner become pregnant, tell your doctor right away.

Male and female fertility may be affected by treatment with BOSULIF.

Do not drive or operate machinery if you feel tired or dizzy, or experience any change in vision while taking BOSULIF.

## INTERACTIONS WITH THIS MEDICATION

### Serious Drug and Drug-Food Interactions

Do not take any products or juice containing grapefruit, star fruit, pomegranate, Seville oranges or similar fruits while taking BOSULIF. They may change the amount of BOSULIF in your body.

While taking BOSULIF, avoid taking drugs that:

- Are used to treat fungal infections such as ketoconazole, itraconazole, voriconazole, posaconazole, and fluconazole
- Are used to treat human immunodeficiency virus (HIV) infections such as lopinavir/ritonavir, atazanavir, indinavir, nelfinavir, saquinavir, darunavir/ritonavir, amprenavir, efavirenz, etravirine and fosamprenavir.
- Are used to treat high blood pressure such as diltiazem, verapamil, bosentan and mibefradil
- Are used to treat depression such as nefazodone and St. John's wort (a herbal preparation obtained without a prescription)
- Are used to treat bacterial infections such as erythromycin, clarithromycin, ciprofloxacin and nafcillin
- Are used to treat tuberculosis such as rifampicin
- Are used to treat epilepsy such as phenytoin and carbamazepine
- Are used to prevent and control nausea (feeling sick) and vomiting, such as aprepitant
- Are used to treat certain types of sleep disorders, such as modafinil
- Are used to treat cancers, such as crizotinib and imatinib
- Are used to treat hepatitis C virus, such as telaprevir
- Are used to treat low sodium, such as conivaptan

**Tell your doctor about the medicines you take, including prescription medicines, non-prescription medicines, vitamins, and herbal supplements.** BOSULIF and certain other medicines can interact with each other and cause serious side effects. Drugs that may interact with BOSULIF include:

- Other cancer medicine such as vandetanib, sunitinib, nilotinib, lapatinib.
- Quinidine, amiodarone and other medicines for heart rhythm problems (anti-arrhythmic drugs).
- Lansoprazole, dexlansoprazole, omeprazole, esomeprazole, pantoprazole, rabeprazole (medicines for reducing stomach acid).
- Amitriptyline and imipramine (medicine for depression).
- Pimozide, ziprasidone, haloperidol (medicine for psychoses).
- Quinine and chloroquine (medicine to treat malaria).
- Domperidone, dolasetron and ondansetron (medicine for nausea and vomiting).

- Formoterol and salmeterol (asthma drugs).
- Water pills, laxatives (medicine that decrease electrolyte levels).

Know the medicines you take. Keep a list of your medicines, both prescription and non-prescription, and show it to your doctor and pharmacist when you get a new medicine. Do not take other medicines with BOSULIF until you have talked with your doctor.

## PROPER USE OF THIS MEDICATION

BOSULIF should be taken with a meal. Swallow BOSULIF tablets whole. Do not cut, crush or dissolve the tablets. Do not drink grapefruit juice or eat grapefruit, grapefruit products, star fruit, pomegranate, Seville oranges and other similar fruits. They may change the amount of BOSULIF in your body.

Always take BOSULIF exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

### Usual Adult Dose (≥18 years of age):

**Patients with newly-diagnosed chronic phase Ph+ CML:**  
400 mg once daily.

**Patients with chronic, accelerated, or blast phase Ph+ CML whose previous medicines to treat Ph+CML have either not worked or not been suitable:** 500 mg once daily.  
Your doctor may adjust the dose.

### Overdose:

If you think you have taken too much BOSULIF contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

If possible, show the doctor the pack, or this leaflet. You may require medical attention.

### Missed Dose:

If dose is missed by less than 12 hours, take your recommended dose. If a dose is missed by more than 12 hours, take your next dose at your regular time on the following day. Do not take a double dose to make up for the forgotten tablets.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

**BOSULIF may cause serious side effects, such as:**

**Liver problems** - Your doctor may do blood tests to check your liver function during treatment with BOSULIF:

- your skin or the whites of your eyes turn yellow
- your urine turns dark or brown (tea color)

**Hepatitis B virus reactivation** – A previous hepatitis B viral infection (an infection of the liver) to become active again when you have had a hepatitis B infection in the past (hepatitis B reactivation), which can be fatal in some cases.

**Kidney problems** – Your doctor may do blood and/or urine tests to check your kidney function before and during treatment with BOSULIF

**Gastrointestinal problems:**

- you have abdominal pain, nausea, diarrhea, or vomiting
- you have blood in your vomit or have black, bloody or tarry stools

**Low blood cell counts:**

- you have signs of infection such as fever, or severe chills
- you have unexpected bleeding or bruising without having an injury

**Your body may hold too much fluid (fluid retention):**

- you have difficulty breathing, chest pain, or a cough
- you have swelling in your hands, ankles, or feet

**Heart problems:**

- dizziness, palpitations or if you faint

Tell your doctor right away if you develop or have developed any of the above serious side effects.

Tell your doctor if you have any side effect that bothers you or that does not go away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Reduction in the number of platelets, red blood cells, white blood cells, and neutrophils (type of white blood cells)		√	
	Diarrhea, vomiting, stomach pain, nausea, decrease of appetite	√		
	Fatigue and headache	√		
	Shortness of breath		√	
	Changes in blood test to determine if BOSULIF is affecting your liver, kidney, and/or pancreas		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Sore throat combined with runny nose (nasopharyngitis)	√		
Skin rash which may be itchy and/or generalized	√		
Feeling of instability (dizziness)		√	
Joint pain	√		
Common	Increased blood pressure		√
	Fever associated with a marked decrease in the number of neutrophils (a type of white blood cells)		√
	Fluid accumulation in the sac-like covering of the heart		√
	Stomach irritation (gastritis)		√
	Fever	√	
	Swelling of hands, feet or face		√
	Weakness, chest pain, pain		√
	Kidney failure, kidney impairment		√
	Influenza, bronchitis	√	
	Toxic damage to the liver, abnormal hepatic function including liver disorder		√
Infection of the lung (pneumonia)		√	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
High level of potassium in the blood, low level of phosphorous in the blood, excessive loss of body fluid (dehydration)		√	
Back pain, pain in the muscle	√		
Alteration of the sense of taste (dysgeusia)	√		
Fluid on the lungs (pleural effusion)		√	
Itching, urticaria (hives), acne	√		
<b>Uncommon</b>	Inflammation of the sac-like covering of the heart (pericarditis)		√
	Blood in stools and throwing up blood		√
	Defect in cardiac rhythm that predisposes to syncope, dizziness and palpitation		√
	Respiratory failure		√
	Allergic reaction, potentially life-threatening (anaphylactic shock)		√
	Abnormally high blood pressure in the arteries of the lungs (pulmonary hypertension)		√
	Severe skin disorder due to an allergic reaction (erythema multiforme), exfoliative (scaly, peeling) rash, skin eruption		√

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Rare</b>			√
	Fever, sore mouth/throat, cough, and muscle aches may occur followed by development of severe red rash that blisters/peels with mouth sores and painful, red, watery eyes.		

*This is not a complete list of side effects. For any unexpected effects while taking BOSULIF, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store at 20°C to 25°C.

Keep BOSULIF and all other medicines, out of the reach and sight of children.

**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/adverse-reaction-reporting.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.*

**MORE INFORMATION**

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

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp>); the manufacturer's website [www.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC  
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