

Medication Information Sheet**ponatinib** (poe na ti nib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Iclusig™

Appearance: tablet

What is this medication for?

- For treating chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL).

What should I do before I have this medication?

- Tell your doctor and pharmacist if you have or had significant medical condition(s), especially if you have or had:
 - ◊ heart problems
 - ◊ liver disease (including hepatitis)
 - ◊ pancreas problems
 - ◊ high blood pressure
 - ◊ stroke, blood clots
 - ◊ diabetes
 - ◊ or any allergies
- People with cancer have a higher risk of getting other cancers or developing blood clots. Some cancer medications may increase these risks, especially if used for a long period of time. Discuss any concerns about this medication with your health care team.
- This drug contains a small amount of lactose. If you cannot tolerate lactose, talk to your doctor or pharmacist.
- Your doctor and pharmacy must be registered with ICLUSIG Controlled Distribution Program. You must register with this program before starting ponatinib.

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding

- If there is ANY chance that you or your partner may become pregnant, you and your partner together must: ► **Use 2 effective forms of birth control at the same time** while receiving this drug: Keep using birth control until at least **6 months** after the last dose. It is unknown if ponatinib affects how birth control pills work. Consider another method of contraception. Discuss with your healthcare team.
- Tell your doctor right away if you or your partner becomes pregnant.
- Do not breastfeed while using this drug.
- This medication may affect fertility (ability to get pregnant)

How is this medication given?

- Swallow whole with a glass of water, with or without food.
- Do not crush or chew the tablets.
- If you miss a dose, skip this and take your next dose as you normally do. Do not take an extra dose to make up for the missed dose.

What else do I need to know while on this medication?

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. They may increase side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- **For mild aches and pain or fever:**
 - If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
 - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.

- **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.

What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
Common Side Effects (in 25 to 49 out of 100 people)	
<p>Abnormal levels of pancreas tests (lipase, amylase)</p> <p>Your doctor may monitor these regularly.</p> <p>Rarely may be severe with pain in your belly extending to your back.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p>Rash; dry, itchy skin (may be severe)</p> <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p> <p>To prevent and treat dry skin,</p> <ul style="list-style-type: none"> • Use skin moisturizer. • Protect your skin from the sun and the cold. • Use sunscreen with UVA and UVB protection and a SPF of at least 30. 	<p>Contact your health care team if no improvement or if severe</p>
<p>Low platelets in the blood</p> <ul style="list-style-type: none"> • Watch for bleeding (such as unusual nosebleeds or bleeding from the gums) or bruising easily (this is rare). 	<p>Get emergency medical help right away</p>

Side effects and what to do	When to contact doctor?
Common Side Effects (in 25 to 49 out of 100 people)	
<ul style="list-style-type: none"> • Very rarely, severe symptoms can happen. If you notice black coloured stools (poo), red or pink coloured urine (pee), red or brown coloured mucus when you cough, severe headache/confusion or bleeding that will not stop, you need to talk to your health care team or go to the nearest emergency room right away. <p>See the Low Platelet Count pamphlet for more information.</p> <p>Fever, chills, infection</p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> • 38.3°C (100.9°F) or higher at any time OR • 38.0°C (or 100.4°F) or higher for at least one hour. <p>While you are getting treatment:</p> <ul style="list-style-type: none"> • Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills). • Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever. • Do not eat or drink anything hot or cold right before taking your temperature. • Wash your hands often to prevent infection. • Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist. <p>If you have a fever, talk to your health care team or go to the closest emergency room.</p> <p>See our Neutropenia (Low white blood cell count) pamphlet for more information.</p>	<p>Get emergency medical help right away</p>
<p>Pains or cramps in the belly</p> <ul style="list-style-type: none"> • If you have constipation or diarrhea it may be causing the pain in your belly. • If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
Common Side Effects (in 25 to 49 out of 100 people)	
<p>Mild swelling in arms and legs; puffiness (may be severe, including rare buildup of fluid around the heart or lungs)</p> <p>To help prevent swelling :</p> <ul style="list-style-type: none"> • Eat a low-salt diet. • Avoid tight fitting clothing. <p>If you have swelling in your legs, keep your feet up when sitting.</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (in 10 to 24 or more out of 100 people)	
<p>Headache; mild joint, muscle pain or cramps</p> <ul style="list-style-type: none"> • Take your pain medication as prescribed by your doctor. • You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. • Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. • Rest often and try light exercise as it may help. 	Contact your health care team if no improvement or if severe
<p>Constipation</p> <p>To help prevent constipation :</p> <ul style="list-style-type: none"> • Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. • Be Active. Exercise can help to keep you regular. • Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation :</p> <ul style="list-style-type: none"> • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do. <p>See the Constipation Pamphlet for more information.</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (in 10 to 24 or more out of 100 peopl)	
<p>Blockage of an artery (blood vessel)</p> <p>It can happen in your heart, chest, brain, belly or limb. It may be more severe and block a big artery and cause :</p> <ul style="list-style-type: none"> • Stroke: you may feel confused and have a sudden loss of vision or trouble speaking or using your arms or legs. • Heart attack: you can have chest pain, shortness of breath, pain in your belly or arm. 	Get emergency medical help right away
<p>Fatigue (tiredness)</p> <ul style="list-style-type: none"> • Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). • Avoid driving or using machinery if you are feeling tired <p>See our Fatigue pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<p>Abnormal liver lab tests</p> <ul style="list-style-type: none"> • You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens. • May be severe, especially in patients whose hepatitis B virus becomes active again • Your doctor may monitor your liver regularly with a blood test. 	Contact your health care team if no improvement or if severe
<p>High blood pressure</p> <ul style="list-style-type: none"> • Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. • If you have a severe headache, severe dizziness, or if you faint, get emergency help right away as it may be a sign your blood pressure is too high. • May rarely be severe and lead to kidney problems 	Contact your health care team if no improvement or if severe
<p>Nausea and vomiting (generally mild)</p> <p>May occur in hours to days after your treatment.</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (in 10 to 24 or more out of 100 peopl)	
<p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take anti-nausea medication(s) as prescribed to you by your doctor. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (e.g. coffee, tea) and alcohol. • Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. <p>Also see Nausea & Vomiting pamphlet for more information.</p>	
<p>Eye problems</p> <ul style="list-style-type: none"> • You may have dry eyes, redness, irritation, pain, tearing, sensitivity to light or blurred vision. • Avoid wearing contact lenses. • You may try artificial tears or ointment. 	Contact your health care team as soon as possible
<p>Tingling, numb fingers and toes</p> <ul style="list-style-type: none"> • May slowly get better after your treatment ends. • Contact your health care team if you have trouble doing up buttons, writing, picking up small objects, have pain or trouble moving. 	Contact your health care team if no improvement or if severe

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Irregular heartbeat, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly
- Swelling and hardening of the vein in an arm or leg
- Sudden severe pain in your upper back or belly, that moves up your neck or down your back, when you didn't hurt yourself
- Weakness on one side of your body
- Trouble seeing or with swallowing
- Unusual pulsating or throbbing feeling in your chest or belly
- Trouble breathing or coughing up blood
- Hair that breaks easily or sensitivity to cold
- Joint pain, fever, confusion and/or kidney problems (difficulty peeing, swelling, unusual weight gain)
- Feel very thirsty and pee more often
- Severe headache, fainting, seizures, confusion, vision loss

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact: _____

Evenings, weekends and holidays: _____

Other Notes:

October 2020 Updated rare side effects section

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health

professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.