

# Ponatinib

Iclusig®

Cancer-directed targeted therapy tablets

## Understanding your treatment

### What is targeted therapy?

This treatment targets specific molecules, which are inside or on the surface of cancer cells. By targeting cancer cells, the targeted therapy limits damage to healthy cells. This type of treatment can be used alone or in combination with other treatments such as chemotherapy.

### How can a targeted therapy help you?

Depending on your type of cancer and the stage of the disease, a targeted therapy can be used to :

- **Destroy** cancer cells
- **Stop** the cancer from spreading
- **Slow** the growth of cancer cells

### How will you feel while on a targeted therapy?

Even though those treatments target cancer cells and limit damage to healthy cells, side effects can still arise.

Not everyone has side effects and each person's experience may differ. Side effects and their severity are not representative of the treatment's effect or lack thereof.

This document presents the most frequent side effects that your targeted therapy causes.

#### Medication

##### **Ponatinib**

Tablets to take by mouth

#### Administration

To be taken once daily

To take with or without food

**On a continuous basis**



A **blood test** will be done throughout your treatment. Depending on the results and side effects, the dose of the medication might be adjusted or the treatment might be interrupted.

## How to take your medication?

- Ponatinib is distributed by a pharmacy different from your usual pharmacy.
- Take your ponatinib tablets, as prescribed, once a day at same time every day. You may take your pills with a large glass of water or juice with or without food. If you have difficulty tolerating it, for example, if it causes a stomach ache, take it while you eat.
- Tablets must be taken whole. Do not chew, split or crush the tablets.
- **If you forget a dose**, you may take it as soon as you remember but do not double your next dose. Try, however, to take your pills at the same time every day and in the same way (with or without food).

## Storing and handling your medicines



- Wash your hands immediately after handling your tablets.
- Keep your medication at room temperature, out of the reach of children and pets as well as protected from light, heat or moisture. Do not keep medicines in the bathroom.
- Don't throw away unused medication at home. Bring it back to your pharmacy to be destroyed safely. You may dispose of the empty containers in your home garbage can.
- Pour the pills from the container into the cap to avoid contact with other surfaces. If it inadvertently comes in contact with the surrounding surface, wash and rub the surface with water and soap.
- Caregivers should wear disposable gloves if they prepare medication for you. You can find disposable gloves at your local community pharmacy.
- Keep your medications in their original container and do not mix them with other drugs. The container should never be reused to put other objects or food.

## How can this treatment affect your daily life?

### Appetite

- Your **appetite may diminish**. Eat more often, in smaller quantities.
- Your **sense of taste may be altered**. Enhance foods with *fines herbes* or lemon juice. Eating fruits and unsweetened candies, chewing non-sugared gums, etc., may mask the metallic taste.
- **Alcohol** in small quantities is allowed and will not affect the efficacy of the treatments.

### Sex life and birth control

- You can have an **active sexual** life during your treatments. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress, etc.).

- It's safe to kiss, to touch, to hold hands, to sleep in the same bed and to cuddle.
- The effect of the ponatinib on male or female fertility is unknown. This medication may have an effect on the menstrual cycle as well as spermatozoid production. However, this does not prevent erection or sexual activity and as such, you can have an active sexual life during your treatments. Pregnancy is possible and this medication could be harmful to the fetus. The use of an effective method of contraception is highly recommended for both men and women while on treatment. Breast-feeding is contraindicated during treatment.

## Foods and medicines to avoid



- **Grapefruit**

You must avoid consuming grapefruit, Seville orange, starfruit, pomelo, pomegranate or foods containing them. The consumption of those foods could increase the side effects of ponatinib.

## Tips and precautions



- **Sit down to urinate and fold down the toilet lid**

Women as well as men should sit down to urinate and fold down the toilet lid before flushing in order to avoid splashing. Flush twice to make sure everything has been flushed away. Follow these precautions during your treatments (or according to instructions from your cancer center).

- **Bodily fluids**

During the treatment period, it's possible that a certain quantity of the medication is found in some bodily fluids or secretions that you produce, such as urine, stools, vomit, sperm and vaginal discharge. In order to protect the environment and those living with you, follow the instructions given by your cancer center about the right way to handle and dispose of the bodily fluids.



- **Over the counter medicines, natural health products and vaccines**

Consult your healthcare team:

- if you intend to take any other medication (with or without a prescription) or natural health products.
- if you need to receive a vaccine.

This could decrease your treatment's efficacy or increase its side effects.

- **Always have on hand the complete list of your medications**

Be sure to always have on hand the complete list of your medications, dietary supplements, vitamins and other natural health products. Give it to you doctor and your pharmacist. It is important to make them aware of any change.

- **Drink plenty of fluids**

It is very important to drink plenty of fluids during the first days of treatment. This decreases the risk of problems related to the rapid destruction of abnormal cells and protects your kidneys.

- Notify your dentist or physician that you are receiving ponatinib should you have to undergo **surgery** while on treatment.

# What are the side effects of your treatment?

This fact sheet aims to let you know the side effects most commonly seen following the administration of your treatment. Please note that when you take any medication, there is a possibility that it causes rare side effects and it is difficult to predict which patients will be affected.

## ADVERSE EFFECTS

## MANAGEMENT

### Skin problems

You might experience some **skin reactions** after starting your treatment. These reactions usually present with:

- A **rash** on the face, neck, chest, back, and arms. This reaction looks like acne and usually disappears within a few weeks after the end of the treatment.
- Your **skin** may become **drier**. **Redness** and **itchiness** may develop.
- Your skin may become more **sensitive to the sun**.

### To help prevent or decrease these reactions:

- Use fragrance-free, alcohol-free mild soap or cleaning products. Also use bath or shower oils to avoid skin dryness.
- Moisturize your skin twice a day with fragrance-free, thick, emollient-based creams like Aveeno®, Neutrogena® or Vaseline Intensive Care® lotion).
- Use non-perfumed creams and cosmetics without alcohol or dye. Use dermatologist-recommended make up (foundation) to mask skin problems.
- Remove make up with a mild cleaning product.
- Avoid sun exposure. In case of unavoidable sun exposure, wear a hat and clothes with long sleeves.
- Avoid over the counter acne products as they can dry skin.
- Use a broad-spectrum sunscreen (SPF of 30 or more).

If despite all these measures, skin reactions appear:

- ✓ **Continue your treatment but contact your healthcare team if :** you develop skin problems such as pimples or redness, scattered on your skin but that are not itchy or tender. Continue to apply the moisturizing cream.
- ⚠ **Continue your treatment and contact your healthcare team as soon as possible if:** you develop skin problems such as pimples or redness, scattered on your skin and they itch or are tender. Continue to apply the moisturizing cream.
- ✗ **Stop your treatment and contact your healthcare team without delay or head to the Emergency Room:** if you develop skin problems, such as pimples or redness all over your body, pain or swelling.

### Decrease in platelets and bleeding

A decrease in platelets may occur. You may bruise or bleed more easily than you normally do.

- Use a tooth brush with soft bristles.
- Consult your pharmacist before taking over the counter medications containing Aspirin® or other anti-inflammatory medication (e.g. Advil®, Motrin®, Aleve®, etc.).
- Contact a member of your healthcare team if you bruise more easily than you normally do or if you have a tendency to bleed easily from the nose or the gums.
- ✗ **Stop your treatment and call your healthcare team or go to the Emergency Room if:** you have prolonged bleeding (more than 20 minutes), or if it's not possible to stop it, or if you have blood in your stools or urine or if you cough up

blood.

### Decrease in white blood cells

A decrease in the **white blood cells** might occur during your treatment. You may be at higher risk of infections.

- Wash your hands often.
- Avoid coming in contact with people who have contagious diseases.
- Contact a member of your healthcare team quickly if you notice any signs of infection (chills, cough, sore throat, pain while you urinate, etc.)
- In case of fever, do not take acetaminophen (Ex: Tylenol®, Atasol®) and anti-inflammatory medication (Ex: Motrin®, Advil®, Aleve®).
- ➔ **Stop your treatment and go to the Emergency Room if:**
  - you have a fever of 38,3 °C (101°F) or above
  - or
  - you have a fever of 38 °C (100,4 °F) twice an hour apart.

### Decrease in red blood cells and fatigue

You may experience a decrease in red blood cells following your treatment. This is called anemia and is characterized by signs of fatigue, pale color, dizziness and shortness of breath.

- Keep active but respect signs of fatigue your body gives you; rest when you feel the need to.
- If you notice one or any of these effects, contact a member of your healthcare team.

### Abdominal pain

Abdominal pain may occur.

- If this happens and is bothering you, contact a member of your healthcare team.

### Constipation

You may experience constipation.

- Exercise if possible.
- Drink lots of liquids (at least 8 glasses a day) (unless otherwise instructed by your doctor).
- Eat foods that are rich in fiber (cereals, fruits and vegetables).
- Communicate with a member of your healthcare team who, if necessary, will recommend appropriate laxatives.

### Headaches

You may experience headaches.

- If this happens and is bothering you, contact a member of your healthcare team who will recommend a medication for pain.



## ADVERSE EFFECTS

## MANAGEMENT

### High blood pressure

High blood pressure might occur.

- Your blood pressure might be checked during your visit with your doctor.
  - A member of your healthcare team might ask you to measure your blood pressure regularly and record it in a diary.
  - If you experience high blood pressure, medication can be prescribed to control it.
- ✔ **Continue your treatment if:** your resting blood pressure is below 140/90 mmHg.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** your blood pressure is above 140/90 mmHg over a short period of time or less than 24 hours.
- ✖ **Stop your treatment and call your healthcare team as quickly as possible if:** your blood pressure is above 160/100 mmHg all or most of the time over a period of 24 hours. **Head to the Emergency Room** if your blood pressure is above 200/120 mmHg or if you have a headache or are confused.

### Fluid retention

A gradual fluid retention may occur with your treatment and may present itself by swelling of the hands, ankles and feet

- Raise your feet while sitting.
  - Avoid wearing tight clothes.
- ✔ **Continue your treatment but contact your healthcare team if:** you have mild swelling: you have gained weight but less than 3 kilos (6,6 pounds).
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you have moderate swelling: you have gained weight, more than 3 kilos (6,6 pounds), but you do not have difficulty breathing.
- ✖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe swelling: you have gained weight, more than 3 kilos (6,6 pounds) and you have difficulty breathing.

### Clot in a blood vessel

If you present one of the following symptoms : severe headaches, visual problems, difficulty talking, loss of coordination, weakness or numbness, chest pain or chest tightness, pain in your calf or leg with local skin warmth and redness or sudden difficulty

- ✖ **Stop your treatment and go to the Emergency Room.**

breathing.

### Muscle and bone pain

You may experience muscle, bone and joint pain and cramps that may occur during your treatment.

- If you present with bone or muscle pain, speak with a member of your healthcare team who will recommend an appropriate pain reliever.

### Nausea

Nausea and vomiting, usually light, may occur during your treatment.

- You may be prescribed medication to be taken if needed if you have nausea.
- ✔ **Continue your treatment if:** you have light nausea that does not prevent you entirely from eating. Make sure to continue your medication prescribed for your nausea.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you have significant nausea, experience vomiting that is partially preventing you from eating. Make sure to continue your medication prescribed for your nausea.
- ➖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe nausea or repeated vomiting that prevents you completely from eating.

### Hair loss

Usually there is **no hair loss** with this treatment.

### RARE ADVERSE EFFECTS THAT CAN BE SEVERE OR SERIOUS

**If the following side effects occur, stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room:**

- Shortness of breath, swelling of the ankles and rapid heartbeats
- Yellow eyes and skin, dark urine (like tea), drowsiness
- Slow or fast heartbeats, dizziness, fainting, chest pain

PHARMACIST: \_\_\_\_\_

PHONE: \_\_\_\_\_ FROM \_\_\_\_ H \_\_\_\_ TO \_\_\_\_ H \_\_\_\_ (MONDAY TO FRIDAY)

This fact sheet has been prepared by a sub-committee of the Comité national de l'évolution de la pratique des soins pharmaceutiques of the Programme québécois de cancérologie of the Ministry of Health and Social Services in consultation with the Comité de l'évolution de la pratique en oncologie of the Institut national d'excellence en santé et en services sociaux.

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## Treatment Diary | Ponatinib 30 days

CYCLE START DATE :

LEGEND (Refer to the information sheet for more details.)

- ✔ Continue your treatment.
- ⚠ Continue your treatment and contact your healthcare team as soon as possible.
- ✖ Stop your treatment and contact your healthcare team without delay or go to the Emergency Room.

		DAYS OF CYCLE																													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
(Record the dose taken)	mg																														
Date (dd-mm)																															
<b>SKIN PROBLEMS</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
✔ Skin problems that you did not have before such as pimples or redness, scattered on your skin but that are <b>not</b> itchy or tender.																															
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✖ Skin problems that you did not have before such as pimples or redness all over your body, pain or swelling.																															
<b>DECREASE IN WHITE BLOOD CELLS</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
✖ You have a fever of 38,3°C (101°F) or above or you have a fever of 38°C (100,4°F) twice an hour apart with or without symptoms of infection.																															
<b>BLEEDING</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
✖ Prolonged bleeding (more than 20 minutes), or if it's not possible to stop it, or blood in the stools or urine or cough up blood.																															



<b>HIGH BLOOD PRESSURE</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Resting blood pressure below 140/90 mmHg.																														
	Blood pressure above 140/90 mmHg over a short period of time or less than 24 hours.																														
	Blood pressure above 160/100 mmHg all or most of the time over a period of 24 hours.																														
<b>NAUSEA AND VOMITING</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Light nausea that does not prevent you entirely from eating.																														
	Significant nausea or if you experience vomiting that is partially preventing you from eating.																														
	Severe nausea or repeated vomiting that prevents you completely from eating.																														
<b>FLUID RETENTION (SWELLING)</b>		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Mild swelling : you have gained weight but less than 3 kilos (6,6 pounds).																														
	Moderate swelling: you have gained weight, more than 3 kilos (6,6 pounds), but you do not have difficulty breathing.																														
	Severe swelling: you have gained weight, more than 3 kilos (6,6 pounds) and you have difficulty breathing.																														



CLOT IN A BLOOD VESSEL	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
You present with one of the following symptoms: severe headaches, visual problems, difficulty talking, loss of coordination, weakness or numbness, chest pain or chest tightness, pain in your calf or leg with local skin warmth and redness or sudden difficulty breathing.																														