

Patient Information Leaflet Ponatinib – ICLUSIG®

## What is ICLUSIG®

Medicine Name	Description
	15 mg, 30 mg, and 45 mg pills: white, round
Ponatinib	AP4 AB

### How should you take your medicine?

Your doctor has determined your medicine dosage.

Swallow whole with a glass of water; do not crush, cut, chew, or dilute the pills.

At a set time, with or without meals.

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

# Dosage – therapy regimen



### How to get the medicine supply?

This medicine is available in local pharmacies.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

## What else do you need to know?

#### Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts, liver and pancreas function tests, blood glucose and cholesterol level), as well as clinical condition monitoring (blood pressure, ECG).

#### Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).

#### Interactions with other medications and/or food

The occurrence of interactions between ICLUSIG® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking. *Example:* While taking ICLUSIG®, it is necessary to avoid using Saint John's wort and grapefruit. Avoid taking medications for

Example: While taking ICLUSIG®, It is necessary to avoid using Saint John's wort and graperruit. Avoid taking medications for hyperacidity.

### What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.

SIDE EFFECTS



ONCOLIEN program of <u>French Oncological Pharmaceutics Society</u> is made available in accordance with the conditions of <u>"CC Attribution-ShareAlike"</u> international license 4.0. Based on work <u>https://oncolien.sfpo.com</u>. Permissions beyond the scope of this license can be obtained at <u>https://www.sfpo.com</u>.

Most common ones	Digestive problems: nausea, vomiting, diarrhea, constipation, and loss of appetite General disorders: water retention, dizziness, fatigue
	Abnormal lab results: low thrombocyte count (thrombocytopenia) and/or multinuclear neutrophil count
	(neutropenia), low hemoglobin level (anemia), abnormal liver and/or pancreas function test
	Pain: pain in bones, muscles, and joints, headaches Skin problems: skin rash, itching
	Respiratory problems: infection, cough, breathing problems
	Cardiac problems, including high blood pressure
	Others: bleedings, fatigue, and sleep disorders
Some patients require special attention	Patients – carriers of hepatitis B virus Patients with diabetes (risk of hyperglycemia)
WHEN TO ALERT THE MEDIC	AL TEAM?
Tell medical personnel if the	Digestive problems
following conditions are present and in the absence	<ul> <li>&gt; Significant and/or rapid weight loss</li> <li>&gt; Very frequent diarrhea, bowel movement over 4 times a day</li> </ul>
of specific medical advice	> Severe abdominal pain
	> Inability to drink for 24 hours and/or eat for about 48 hours
	> Bowel movements fewer than 3 times a week Symptoms suggestive of infection
	> Temperature > 38.5 °C
	> Cough, throat pain, pain on urination, diarrhea with fever
	Symptoms suggestive of hemorrhage > Blood in stool or in vomit
	> Hematomas (bruises), nose bleedings
	Respiratory problems
	<ul> <li>Increasing constant cough or problems breathing</li> <li>Pain that prevents you from doing your normal activities</li> </ul>
	> Headaches and/or joint pain
	Symptoms suggestive of water retention
	Fast and unexpected weight gain
	Symptoms suggestive of heart or vessels disorder
	<ul> <li>Headaches, buzzing in the ears, and/or dizziness</li> <li>Blood pressure increase</li> </ul>
	Shortness of breath, high palpitations, or chest pain or tightness
	> Red, warm to the touch, and painful calf
	Symptoms suggestive of neurological disorder > Weakness in one side of the body, severe headaches, convulsions, confusion, problems speaking,
	vision changes, or severe dizziness
HOW TO PREVENT SIDE EFF	
Skin care	<b>Opt for</b> mild soap and moisturizer, pat skin dry. <b>Avoid</b> using any skin irritating products. <i>For sun protection</i> <b>use</b> broad spectrum sunscreen and <b>avoid</b> sun exposure.
Weight	Regularly check your weight in case of digestive problems or water retention.
Water retention (limb swellings)	Avoid wearing tight clothing, socks, and shoes. Put your feet in an elevated position.
Infection	Don't forget the antibiotic prescribed by your doctor.
	Avoid visiting high risk areas (crowds, contact with sick people,). A flu and pneumococcal infection vaccine
	might be recommended for you: it will protect you.
Blood pressure control	Elevated blood pressure needs to be corrected. <b>Taking arterial pressure regularly</b> is recommended. Pharmacists can help you take your blood pressure. You can also ask to do it by yourself using an automatic blood pressure monitor.
Fations / inits and /	· ·
Fatigue / joint pain / constipation	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports Alternate periods of activity and rest
Bleedings	Avoid taking anti-inflammatory drugs (ibuprofen, aspirin)
-	Notify your doctor:
	<ul> <li>&gt; if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed</li> <li>&gt; about surgical or dental intervention.</li> </ul>
HOW TO ADAPT YOUR DIET?	
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas.
	Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol. Drink more water.
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes.
	Limit consumption of fatty, fried, and spicy foods.
Water retention	Opt for a low salt diet.
Constipation	Opt for a high fiber diet. Drink more water.



ONCOLIEN program of <u>French Oncological Pharmaceutics Society</u> is made available in accordance with the conditions of <u>"CC Attribution-ShareAlike"</u> international license 4.0. Based on work <u>https://oncolien.sfpo.com</u>. Permissions beyond the scope of this license can be obtained at <u>https://www.sfpo.com</u>.