

INFORMATION FOR THE HEALTHCARE PROVIDER

This patient is being treated with PrICLUSIG™ (as ponatinib hydrochloride).

WARNING: ICLUSIG HAS BEEN REPORTED TO CAUSE VASCULAR OCCLUSION, INCLUDING THROMBOEMBOLISM, AND CONGESTIVE HEART FAILURE.

Vascular occlusion

Arterial and venous thrombosis and occlusions, including fatal

myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures have occurred in ICLUSIG-treated patients.

Patients with and without cardiovascular risk factors, including patients less than 50 years old, experienced these events.

Monitor for evidence of thromboembolism and vascular occlusion.

Interrupt or stop ICLUSIG immediately for vascular occlusion.

Congestive heart failure

Fatal and serious heart failure or left ventricular dysfunction has occurred in ICLUSIG-treated patients.

Monitor cardiac function

Interrupt or stop ICLUSIG for new or worsening heart failure.

Other potentially serious side effects observed in ICLUSIG clinical trials included¹:

- Hemorrhagic events (in some cases fatal)
- Hepatotoxicity/hepatic failure (in some cases, fatal)

- Myelosuppression (thrombocytopenia, neutropenia, and anemia)
- Pancreatitis

For a complete list of adverse reactions associated with ICLUSIG, including managing options, please refer to the *ICLUSIG Product Monograph*.

References:

1. *ICLUSIG Product Monograph*
2. CDP website (www.iclusigcdp.ca)



Ponatinib Tablets, 15 mg and 45 mg
(as ponatinib hydrochloride)

ICLUSIG Patient Alert/Wallet Card: This patient alert/wallet card contains important safety information that you need to be aware of before and during treatment with ICLUSIG. You should receive this card with the first prescription and with each refill. Please carry this card with you at all times. Show this card to any doctor or healthcare professional involved in your care to make sure they know you are receiving ICLUSIG. August 2018

INFORMATION FOR THE PATIENT

PrICLUSIG™ (as ponatinib hydrochloride) can cause serious side effects, including:

Blood clots or blocked blood vessels (arteries and veins)

Blood clots or blockage in blood vessels may lead to heart attack, stroke, or death. Emergency surgery or treatment in a hospital may be required.

Heart problems

ICLUSIG can cause heart problems, including heart failure, which can be serious and may lead to death. Irregular slow or fast heartbeats and heart attack may also occur.

Additional side effects

Other serious side effects that have been associated with ICLUSIG include liver problems, inflammation of the pancreas, severe bleeding, and low blood cell counts.

Do not stop taking ICLUSIG, or change your dose, unless told by your doctor.

Get medical help right away if you get any of the following symptoms:

- Chest pain or pressure
- Pain in your arms, legs, back, neck, or jaw
- Fast or irregular heartbeats
- Shortness of breath
- Decreased alertness, lethargy, or confusion
- Unusual bleeding, including blood in stool, vomiting blood, dark or tarry stool, easy bruising, or nose bleeding
- Dark-colored urine
- Numbness or weakness on one side of your body

- Difficulty talking
- Headache
- Dizziness or feeling faint
- Severe stomach area pain
- Decreased vision or loss of vision
- Fever in association with other signs of infection, chills
- Yellow-colored skin and eyes

These are not all the possible side effects of ICLUSIG. For more information, please refer to the *ICLUSIG Medication Guide*, or speak to your healthcare professional.

Patient's name:

Haematologist's/oncologist's name:

Haematologist's/oncologist's contact number:

ICLUSIG treatment started on:
