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2. Ponatinib

## **Ponatinib**

Generic name: ponatinib [ poe-NA-ti-nib ]

Brand name: Iclusig

Dosage form: oral tablet (10 mg; 15 mg; 30 mg; 45 mg)

Drug classes: BCR-ABL tyrosine kinase inhibitors, Multikinase inhibitors, VEGF/VEGFR inhibitors

Medically reviewed by Philip Thornton, DipPharm. Last updated on Aug 23, 2023.

Uses Warnings Before taking Dosage Side effects Interactions

## What is ponatinib?

Ponatinib is a cancer medicine that interferes with the growth of some cancer cells.

Ponatinibis used in adults to treat a type of blood cancer called chronic myeloid leukemia (CML), or Philadelphia chromosome positive acute lymphoblastic leukemia (ALL).

Ponatinib is usually given after other similar medications have been tried without success.

## **Warnings**

Ponatinib may cause heart or blood vessel problems that could lead to heart attack, stroke, or death.

Call your doctor or get emergency medical help if you have: chest pain spreading to your jaw or shoulder, shortness of breath, dizziness, severe stomach pain, swelling in your legs, sudden numbness or weakness, headache, or problems with vision or speech.

Ponatinib may also harm your liver. Call your doctor right away if you have upper stomach pain with loss of appetite, dark urine, bruising, or yellowing of your skin or eyes.

## Before taking this medicine

You should not use ponatinib if you are allergic to it.

To make sure ponatinib is safe for you, tell your doctor if you have ever had:

- heart failure, high blood pressure, heart rhythm problems;
- long QT syndrome (in you or a family member);
- a stroke or blood clot;

- · diabetes;
- · high cholesterol;
- · liver disease:
- bleeding problems;
- lactose intolerance (tablets may contain lactose);
- · pancreatitis; or
- if you've had surgery within the past 2 weeks.

You may need to have a negative pregnancy test before starting this treatment.

**Ponatinib may harm an unborn baby.** Use effective birth control to prevent pregnancy while you are using ponatinib and for at least 3 weeks after your last dose.

This medicine may affect fertility (ability to have children) in women. However, it is important to use birth control to prevent pregnancy because ponatinib can harm an unborn baby.

You should not breastfeed while using ponatinib and for at least 6 days after your last dose.

Ponatinib pregnancy and breastfeeding warnings (more detail)

### How should I take ponatinib?

Take ponatinib exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Ponatinib is usually taken once daily, with or without food.

Swallow the tablet whole and do not crush, chew, or break it.

You may need frequent medical tests to be sure ponatinib is not causing harmful effects. Your cancer treatments may be delayed based on the results.

If you need surgery, tell the surgeon ahead of time that you are using ponatinib. You may need to stop using the medicine at least 1 week before a surgery.

Do not stop taking ponatinib or change your medication dose without your doctor's advice.

Store at room temperature away from moisture and heat.

## **Dosing information**

Usual Adult Dose of Ponatinib for Chronic Myelogenous Leukemia:

Chronic phase chronic myeloid leukemia (CP-CML):

- -Initial Dose: 45 mg orally once a day
- -Upon achievement of 1% BCR-ABL1 or less (standardized according to International Scale): 15 mg orally once a day
- -For loss of response: Re-escalate to a previously tolerated dosage of 30 mg or 45 mg orally once a day

Accelerated phase chronic myeloid leukemia (AP-CML), blast phase chronic myeloid leukemia (BP-CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL):

-Initial dose: 45 mg orally once a day

### Usual Adult Dose of Ponatinib for Acute Lymphoblastic Leukemia:

Chronic phase chronic myeloid leukemia (CP-CML):

- -Initial Dose: 45 mg orally once a day
- -Upon achievement of 1% BCR-ABL1 or less (standardized according to International Scale): 15 mg orally once a day
- -For loss of response: Re-escalate to a previously tolerated dosage of 30 mg or 45 mg orally once a day

Accelerated phase chronic myeloid leukemia (AP-CML), blast phase chronic myeloid leukemia (BP-CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL):

-Initial dose: 45 mg orally once a day

#### Comments:

- -The optimal dose has not been identified for AP-CML, BP-CML, and Ph+ ALL.
- -Consider dose reduction for AP-CML patients who have achieved major cytogenic response.
- -Continue treatment until loss of response or unacceptable toxicity.
- -Drug discontinuation should be considered if patient response has not occurred by 3 months (90 days).
- -This drug is not indicated and is not recommended for the treatment of patients with newly diagnosed chronic phase chronic myeloid leukemia (CP-CML).

#### Uses:

- -For the treatment of adult patients with CP-CML with resistance or intolerance to at least two prior kinase inhibitors
- -For the treatment of adult patients with AP-CML, or BP-CML or Ph+ ALL for whom no other kinase inhibitors are indicated
- -For the treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL
- Detailed Ponatinib dosage information

## What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid while taking ponatinib?

Grapefruit may interact with ponatinib and lead to unwanted side effects. Avoid the use of grapefruit products.

### Ponatinib side effects

Get emergency medical help if you have signs of an allergic reaction to ponatinib: hives; difficult breathing; swelling of

your face, lips, tongue, or throat.

Ponatinib may cause heart or blood vessel problems that could lead to heart attack or stroke. Call your doctor right away or get emergency medical help if you have:

- heart attack symptoms chest pain or pressure, pain spreading to your jaw or shoulder, feeling short of breath;
- signs of a stroke sudden numbness or weakness (especially on one side of the body), sudden severe headache, slurred speech, problems with vision or balance; or
- signs of a blood clot severe stomach pain, pain or swelling in your arms or legs, coughing up blood.

Call your octor at once if you have:

- dizziness, confusion, headache, change in mental status;
- · a seizure;
- swelling, rapid weight gain, feeling short of breath;
- a wound that will not heal;
- eye problems vision problems, eye pain or swelling, bleeding in the eye, increased sensitivity to light, flashes of light or "floaters" in your vision;
- heart problems chest pain, shortness of breath, fast or pounding heartbeats, feeling like you might pass out;
- a hole or tear in your stomach or intestine severe pain or swelling in your stomach with a high fever;
- low blood cell counts fever, chills, tiredness, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet;
- nerve problems muscle weakness, trouble moving your eyes or other parts of your face, tingling, burning pain, numbness in your hands and feet;
- severe bleeding nosebleeds, bloody or tarry stools, pink or brown urine, heavy menstrual periods, coughing up blood or vomit that is bloody or looks like coffee grounds;
- signs of liver or pancreas problems loss of appetite, upper stomach pain (that may spread to your back), nausea or vomiting, fast heart rate, dark urine, jaundice (yellowing of the skin or eyes).

Common ponatinib side effects may include:

- dry skin, rash;
- stomach pain, nausea, vomiting, diarrhea, constipation;
- headache, muscle or joint pain;
- pain in your arms, hands, legs, or feet;
- increased blood pressure; or
- · fever, tired feeling.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Ponatinib side effects (more detail)

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## What other drugs will affect ponatinib?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Many drugs can interact with ponatinib. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed here. Tell your doctor about all your current medicines and any medicine you start or stop using.

1 Ponatinib drug interactions (more detail)

### Does ponatinib interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

ponatinib	
+	
Enter a drug name	Add

### More about ponatinib

- · Check interactions
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### **Patient resources**

#### Other brands

Iclusig

### Professional resources

• PONATinib Hydrochloride monograph

#### Other brands

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### Related treatment guides

- Acute Lymphoblastic Leukemia
- Chronic Myelogenous Leukemia

### **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use ponatinib only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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#### **DRUG STATUS**

### **Availability**

Rx Prescription only

### **Pregnancy & Lactation**

ন্য Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

### **Approval History**

Drug history at FDA

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### **Images**

Iclusig (ponatinib) 15 mg (A5)





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