

ORAL CHEMOTHERAPY EDUCATION



PONATINIB

Name of your medication

Generic name — Ponatinib (poh-NA-tih-nib)
Brand name — Iclusig® (i-KLOO-sig)

Approved uses

Ponatinib is used to treat adults with chronic myeloid leukemia (CML) that is Philadelphia chromosome–positive (Ph+) and acute lymphoblastic leukemia (ALL) that is Ph+.

Dose and schedule

Taking ponatinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of ponatinib is 45 milligrams (45 mg) to be taken by mouth at a scheduled time once a day.
- Ponatinib can be taken with or without food, but at the same time each day.
- Ponatinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow ponatinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of ponatinib, do not take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time.
- Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Drug and food interactions

- Ponatinib has many drug interactions, please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Grapefruit or grapefruit juice may interact with ponatinib; avoid eating or drinking these during your treatment with ponatinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle ponatinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store ponatinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep ponatinib out of reach of children and pets.
- Leave ponatinib in the provided packaging until it is ready to be taken.
- Whenever possible, give ponatinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give ponatinib to you, they may also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)

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3. Gently transfer the ponatinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using:
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn
 - If you have any unused ponatinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of ponatinib.
 - If you are traveling, put your ponatinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Ponatinib

Below are common side effects that have been known to happen in about one third or more of patients taking ponatinib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Increased blood pressure	Routinely take your blood pressure. Record your blood pressure in a journal or diary and report this information to your physician. Contact your healthcare provider for high blood pressure or if symptoms such as the following occur: <ul style="list-style-type: none">• Headache• Dizziness• Chest pain• Shortness of breath• Fluid retention, weight gain, or swelling

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Possible Side Effect	Management
<p>Rash or itchy skin</p>	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing. • Avoid using perfumes and cologne as these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs between 10 am–4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. • Use lip balm with at least SPF 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

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Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High glucose levels • High lipase levels • Low phosphorous levels • Low calcium levels 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently, and do not pick your nose. • Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or hold your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.

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Possible Side Effect	Management
<p>Abdominal pain</p>	<p>Abdominal pain or discomfort may occur. Report any serious pain or symptoms to your care provider immediately.</p> <p>If these side effects occur with nausea and vomiting, you might have inflammation of your pancreas (pancreatitis).</p>
<p>Headache</p>	<p>Ask your provider what you may use to help with this discomfort. Contact your care provider right away if your headache:</p> <ul style="list-style-type: none"> • Follows a head injury • Is severe or starts suddenly • Does not go away after 3 days • Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, made worse by coughing or lowering the head, rash, weakness in an arm or leg, or numbness
<p>Constipation</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Stay active and exercise, if possible. • Eat foods high in fiber like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in 3 or more days.</p> <p>Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener such as docusate (Colace®) and/or laxative such as senna (Senokot®) may be helpful. If these do not help within 48 hours, tell your provider.</p>
<p>Changes in liver function</p>	<p>Your liver function should be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Unusual bleeding or bruising

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Possible Side Effect	Management
Joint pain	<ul style="list-style-type: none"> Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Stay as active as possible, but know that it is okay to rest as needed. Tell your care provider if pain interferes with your activity. <p>If the pain bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
Fever	<p>You may feel hot, cold and shivery, achy or dizzy. This usually starts during the first month of therapy but could happen at any time.</p> <ul style="list-style-type: none"> Tell your doctor immediately if you have a fever 100.4° F <p>Ask your doctor if you can take medicine to help with the fever.</p>

Serious side effects of ponatinib

- Ponatinib can cause serious cardiovascular events, including heart failure, fatal myocardial infarction (heart attack), stroke, and venous thromboembolism (blood clot). Notify your care provider immediately if you experience any of the following symptoms: shortness of breath; significant weight gain; swelling in the arms or legs; numbness or weakness on one side of your body; trouble speaking or thinking; change in balance; change in eye sight; chest, arm, leg, back, neck, or jaw pain or pressure.
- While taking ponatinib you may lose sensitivity in your hands or feet. Talk to your care provider about ways to resolve this side effect.
- Ponatinib may be harmful to your pancreas. Speak to your care provider to know when you need to have laboratory tests done to monitor your pancreas. Seek medical attention if you have severe abdominal pain or tenderness, fever, or vomiting.
- Ponatinib may be harmful to your eyes. Be sure to inform your care provider of any issue you have with your vision, or pain in your eyes. Your provider may stop treatment with ponatinib if your eyes are affected.
- Some patients taking ponatinib have experienced tumor lysis syndrome when starting treatment. Your healthcare provider may do blood tests to check for this side effect.
- A condition called reversible posterior leukoencephalopathy syndrome can occur while taking ponatinib. Call your healthcare provider immediately if you have headaches, seizures, confusion or changes in vision.
- If you need to have a surgical or dental procedure, tell your doctor that you are taking ponatinib. Ponatinib may need to be stopped until your wound heals after some types of surgery.
- Tell your doctor if you notice swelling in your hands, feet, or legs.
- Ponatinib is not recommended for the treatment of patients with newly diagnosed chronic phase CML due to increased risk of serious side effects.
- Ponatinib can cause liver failure. Notify your care provider immediately if you have signs of liver problems like dark urine, feeling tired or not hungry, have an upset stomach or stomach pain, have light-colored stools, are throwing up, or have yellow skin or eyes.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Since ponatinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take ponatinib, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or ponatinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking ponatinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of three weeks after the last dose of ponatinib.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking ponatinib and for six days after the last dose of ponatinib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on ponatinib, and you are encouraged to ask your care provider.

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National Community Oncology
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PASSION FOR PATIENTS



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Obtaining medication

Talk with your care provider about the process for obtaining your ponatinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <http://www.iclusig.com>

Product prescribing information: <http://www.iclusig.com/pi>

Product resources: <http://www.iclusig.com/support-and-resources>

Updated — March 6, 2020

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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