

Ponatinib (Iclusig)

About This Medicine

PONATINIB (poe NA ti nib) treats leukemia. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea
- Pain in your abdomen
- Constipation (unable to move bowels)
- Tiredness
- Fever
- Swelling of the hands, feet, or any other part of the body
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Pain in the joints
- Headache
- Rash
- Dry skin
- Changes in your pancreas and liver function
- High blood pressure
- Blood clots and events such as stroke and heart attack, which can be life-threatening. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.

Note: Each of the side effects above was reported in greater than 20% of people treated with ponatinib. All possible side effects are not included. Your side effects may be different depending on your cancer

diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Severe bone marrow suppression
- Blurred vision or other serious changes in eyesight including loss of vision
- Changes in your heart function such as abnormal heartbeat and congestive heart failure - your heart is not pumping blood as well as it should be, and fluid can build up in your body. These changes can be life-threatening.
- Severe abnormal bleeding which can be life-threatening
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your care team know right away.**
- Severe high blood pressure
- Severe inflammation of your pancreas
- Severe changes in your liver function, which can cause liver failure and be life-threatening.
- Tumor lysis syndrome: This medicine may act on the cancer cells very quickly. This may affect how your kidneys work.
- Severe swelling of your legs, ankles and/or feet, or other areas, which can be life-threatening. You may have trouble breathing because of fluid build-up around your lungs and/or your heart.
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the medicine. These effects get better in some people after the medicine is stopped but it does not get better in all people.
- Slow wound healing and perforation- an abnormal hole in your stomach, intestine, esophagus, or other organ, which can be life-threatening.

Note: *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.*

Important Information

- Ponatinib may cause slow wound healing. It should not be given within 1 week of planned surgery and for at least 2 weeks and until adequate wound healing following major surgery. If you must have emergency surgery or have an accident that results in a wound, tell the care team that you are on ponatinib.

How to Take Your Medicine

- Swallow the medicine whole with or without food. Do not crush, break, cut, chew, or dissolve tablets.
- **Missed dose:** If you miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.



- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- If you throw up, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help lessen or stop your constipation.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- Moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.



- Use an electric shaver instead of a razor.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of ponatinib in your body which could make side effects worse.
- This medicine contains lactose. Let your care team know if you are lactose intolerant.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with ponatinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Feeling dizzy or lightheaded
- Headache that does not go away
- Confusion
- Extreme tiredness and/or coma
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Blurry vision, changes in your eyesight, or eye pain
- Numbness, tingling, or pain in your hands and feet
- Pain in your abdomen that does not go away
- Severe pain in your abdomen that may spread to your back
- Wheezing and/or trouble breathing
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Your leg is swollen, red, warm, and/or painful
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or



sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**

- Tiredness that interferes with your daily activities
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Difficulty swallowing
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures
- Swelling of the hands, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Pain that does not go away, or is not relieved by prescribed medicines
- Dry skin that is bothersome
- New rash and/or itching or a rash that is not relieved by prescribed medicines

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 3 weeks after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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