

## Ponatinib (Iclusig)

---

### About This Drug

Ponatinib is used to treat cancer. It is given orally (by mouth).

### 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 (fatigue), and raise your risk of bleeding.
- Nausea
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Tiredness
- Fever
- Swelling of your legs, ankles and/or feet.
- 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.
- Joint pain
- Headache
- Rash
- Dry skin
- Changes in your pancreas and liver function
- Blood clots and events such as stroke and heart attack
- High blood pressure

**Note:** Each of the side effects above was reported in 20% or greater of patients treated with ponatinib. Not all possible side effects are included above.

### Warnings and Precautions

- Severe bone marrow suppression
- Blurred vision or other changes in eyesight including loss of vision



- Changes in the tissue of the heart, which can be life-threatening. Some changes may happen that can cause your heart to have less ability to pump blood or cause heart attack. You may have abnormal heartbeats.
- Severe abnormal bleeding which can be life-threatening. 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.
- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, hallucinations (see or hear things that are not there), have trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, seizures or coma. **If you start to have any of these symptoms let your doctor know right away.**
- Severe high blood pressure
- Severe inflammation of your pancreas, which may cause nausea, vomiting, and pain in the abdomen.
- Severe changes in your liver function, which can cause liver failure and be life-threatening.
- Tumor lysis syndrome: This drug may act on the cancer cells very quickly. This may affect how your kidneys work.
- Severe swelling of your legs, ankles and/or feet 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 drug. These effects get better in some people after the drug is stopped but it does not get better in all people.
- Slow wound healing and perforation, which is a hole in your stomach, intestine, esophagus, or other organ, which may 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 medical 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 doctor that you are on ponatinib.

## How to Take Your Medication

- Swallow the medicine whole with or without food. Do not crush, break, cut or chew tablets.
- **Missed dose:** If you vomit or miss a dose, take your next dose at the regular time, and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.



- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **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 medication 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 nurse or your doctor how to dispose of unused medicine.

## Treating Side Effects

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, 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, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse 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 doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor 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.
- Get regular exercise. If you feel too tired to exercise vigorously, try taking a short walk.
- 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 doctor or nurse 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 nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.

## Food and Drug 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 medication contains lactose. Let your doctor know if you are lactose intolerant.
- Check with your doctor or pharmacist 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 drug interactions with ponatinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking ponatinib as this may lower the levels of the drug in your body, which can make it less effective.

## When to Call the Doctor

Call your doctor or nurse 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
- Easy bleeding or bruising
- Headache that does not go away
- Confusion and/or agitation
- 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.**
- Hallucinations
- Trouble understanding or speaking
- Blurry vision or changes in your eyesight
- Numbness or lack of strength to your arms, legs, face, or body
- Numbness, tingling, or pain in your hands and feet
- Pain in your chest or abdomen that does not go away
- Dry cough or coughing up blood
- Wheezing and/or trouble breathing
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Your leg or arm 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.**

- Blood in your urine, vomit (bright red or coffee-ground) and/or stools (bright red, or black/tarry)
- Tiredness or weakness 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
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Decreased urine, or very dark urine
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures
- Swelling of your legs, ankles, and/or feet
- Weight gain of 5 pounds in one week (fluid retention)
- Pain that does not go away, or is not relieved by prescribed medicines
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- If you think you may be pregnant

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 3 weeks after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 6 days after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In women, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on egg banking.

Revised January 2021

