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Ponatinib

pronounced as (poe na' ti nib)

IMPORTANT WARNING:

Ponatinib may cause serious or life-threatening blood clots in your legs or lungs, heart attacks, or strokes. Tell your doctor if you have or have ever had a blood clot in your lungs or legs; a stroke; high blood pressure; hyperlipidemia (high levels of cholesterol in your blood); a slow, fast, or irregular heartbeat; peripheral vascular disease (narrowing of blood vessels in feet, legs, or arms causing numbness, pain, or coldness in that part of the body); a heart attack; or heart disease. If you experience any of the following symptoms, call your doctor immediately: chest pain; shortness of breath; dizziness or fainting; sudden confusion or trouble speaking or understanding; sudden numbness or weakness of face, arm, or leg on one side of the body; sudden severe headache; leg, arm, back, neck, or jaw pain; feeling of warmth in the lower leg; or swelling of the feet, ankles, or lower legs.

Ponatinib may cause serious or life-threatening heart failure (condition in which the heart is unable to pump enough blood to the other parts of the body) and arrhythmias (abnormal heart rhythms). Tell your doctor if you have or have ever had heart problems, including heart failure, QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death); or a slow, fast, or irregular heartbeat. If you experience any of the following symptoms, call your doctor immediately: shortness of breath; chest pain; fast, irregular, or pounding heartbeat; dizziness; or fainting.

Ponatinib may cause serious or life-threatening damage to the liver. Tell your doctor if you have or have ever had liver disease or problems with your liver. If you experience any of the following symptoms, call your doctor immediately: itching, yellow eyes or skin, dark urine, or pain or discomfort in the right upper stomach area.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests before you start and during your treatment to check your body's response to ponatinib.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with ponatinib and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website

(<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>

[<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Ponatinib is used to treat certain types of chronic myeloid leukemia (CML; a type of cancer of the white blood cells), including treatment in people who can no longer benefit from other medications for CML or who cannot take these medications because of side effects. Ponatinib is also used to treat certain types of acute lymphoblastic leukemia (ALL; a type of cancer of the white blood cells) in people who can no longer benefit from other medications for leukemia or who cannot take these medications because of side effects. Ponatinib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps stop the spread of cancer cells.

How should this medicine be used?

Ponatinib comes as a tablet to take by mouth. It is usually taken once a day with or without food. Take ponatinib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ponatinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole; do not split, chew, or crush them.

Your doctor may need to delay your treatment, adjust your dose, or permanently stop your treatment of ponatinib depending on your response to treatment and any side effects that you experience. Talk to your doctor about how you are feeling during your treatment. Continue to take ponatinib even if you feel well. Do not stop taking ponatinib without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking ponatinib,

- tell your doctor and pharmacist if you are allergic to ponatinib, any other medications, lactose, or any of the ingredients in ponatinib tablets. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: ketoconazole (Nizoral); medications to reduce stomach acid, such as lansoprazole (Prevacid); and rifampin (Rifadin, Rimactane, in Rifamate, in Rifater). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with ponatinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

- tell your doctor if you have or have ever had a bleeding problem; diabetes; pancreatitis (swelling of the pancreas, a gland behind the stomach that produces substances to help with digestion); or if you are lactose intolerant (inability to digest dairy products). Also, tell your doctor if you drink or have ever drunk large amounts of alcohol.
- you should know that ponatinib may decrease fertility in women. However, you should not assume that you or your partner cannot become pregnant. Tell your doctor if you are pregnant or plan to become pregnant. If you are female, you will need to take a pregnancy test before you start treatment. You should use birth control to prevent pregnancy during your treatment with ponatinib and for 3 weeks after you stop taking the medication. Talk to your doctor about types of birth control that will work for you. If you become pregnant while taking ponatinib, call your doctor immediately. Ponatinib may harm the fetus.
- tell your doctor if you are breastfeeding or plan to breastfeed. You should not breastfeed while taking ponatinib and for 6 days after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking ponatinib. If you are scheduled to have surgery, your doctor will tell you to stop taking ponatinib for at least 7 days before the surgery or procedure. Your doctor will tell you when to start taking ponatinib again after your surgery.
- you should know that your blood pressure may increase during your treatment with ponatinib. Your doctor will probably monitor your blood pressure during your treatment.

What special dietary instructions should I follow?

Do not eat large amounts of grapefruit or drink grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Ponatinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- rash
- dry skin
- diarrhea
- constipation
- hair loss
- white patches or sores on the lips or in the mouth and throat
- loss of appetite
- weight loss
- cough

- difficulty falling asleep or staying asleep
- back, bone, joint, limb, or muscle pain

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, stop taking ponatinib and call your doctor immediately or get emergency medical treatment:

- unusual bruising or bleeding
- bloody or black, tarry stools
- blood in the urine
- bloody vomit
- unusual vaginal bleeding or heavier than usual menstrual bleeding
- vomit that looks like coffee grounds
- frequent nose bleeds
- coughing up blood
- dry, red, painful, or irritated eyes
- sensitivity to light
- blurred vision, floaters, double vision, or other vision changes
- wounds that do not heal
- fever, sore throat, chills, or other signs of infection
- changes in taste; muscle weakness; drooping eyelids or part of face; tingling, burning, pain, or loss of feeling in hands or feet
- headache, seizures, confusion, problems thinking, or changes or loss of vision
- decreased urination
- extreme tiredness or weakness
- weight gain
- swelling of your face, hands, feet, ankles, or lower legs
- pain, swelling, or tenderness in the abdomen (stomach area)
- nausea
- vomiting
- ongoing pain that begins in the stomach area but may spread to the back

Ponatinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online

(<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- fever, sore throat, chills, and other signs of infection
- rapid, irregular, or pounding heartbeat
- tiredness
- chest pain

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Iclusig[®]

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