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## Ibrutinib

pronounced as (eye broo' ti nib)

### Why is this medication prescribed?

#### Ibrutinib is used:

- to treat people with mantle cell lymphoma (MCL; a fast-growing cancer that begins in the cells of the immune system) who have already been treated with at least one other chemotherapy medication,
- to treat people with chronic lymphocytic leukemia (CLL; a type of cancer that begins in the white blood cells) and small lymphocytic lymphoma (SLL; a type of cancer that begins mostly in the lymph nodes),
- to treat people with Waldenstrom's macroglobulinemia (WM; a slow-growing cancer that begins in certain white blood cells in your bone marrow),
- to treat people with marginal zone lymphoma (MZL; a slow growing cancer that begins in a type of white blood cells that normally fights infection) who have already been treated with a certain type of chemotherapy medication,
- and to treat people with chronic graft vs host disease (cGVHD; a complication of hematopoietic stem-cell transplant [HSCT; a procedure that replaces diseased bone marrow with healthy bone marrow] that may start a while after the transplant and last for a long time) after being treated unsuccessfully with 1 or more medications.

Ibrutinib is in a class of medications called kinase inhibitors. It works by blocking the action of the abnormal protein that signals cancer cells to multiply. This helps stop the spread of cancer cells.

### How should this medicine be used?

Ibrutinib comes as a capsule and a tablet to take by mouth. It is usually taken once daily. Take ibrutinib 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 ibrutinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the **capsules** whole with a glass of water; do not open, break, or chew them. Swallow the **tablets** whole with a glass of water; do not cut, crush or chew them.

If you are receiving obinutuzumab (Gazyva) injection or rituximab (Rituxan) injection, your doctor may tell you to take your dose of imbrutinib before you receive your injection.

Your doctor may decrease your dose, or interrupt or discontinue your treatment. This depends on how well the medication works for you and the side effects you experience. Talk to your doctor about how you are feeling during your treatment. Continue to take ibrutinib even if you feel well. Do not stop taking ibrutinib without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

## 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 ibrutinib,

- tell your doctor and pharmacist if you are allergic to ibrutinib, any other medications, or any of the ingredients in ibrutinib capsules or tablets. Ask your pharmacist 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: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); antifungals such as fluconazole (Diflucan), itraconazole (Onmel, Sporanox), ketoconazole (Nizoral), posaconazole (Noxafil), and voriconazole (Vfend); antiplatelet medications such as clopidogrel (Plavix), prasugrel (Effient), ticagrelor (Brilinta), and ticlopidine; aprepitant (Emend); carbamazepine (Carbatrol, Epitol, Tegretol, Teril); clarithromycin (Biaxin, Prevpac), digoxin (Lanoxin); diltiazem (Cardizem, Cartia, Tiazac, others); erythromycin (E.E.S., Erythrocin, others), certain medications to treat human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as efavirenz (Sustiva, in Atripla), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); methotrexate (Otrexup, Rasuvo, Trexall, Xatmep); nefazodone; phenytoin (Dilantin, Phenytek); rifampin (Rifadin, Rifamate, Rimactane, others); verapamil (Calan, Covera, in Tarka, others); and telithromycin (no longer available in the U.S.; Ketek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor what herbal products you are taking, especially St. John's Wort.
- tell your doctor if you have an infection or recently had surgery. Also tell your doctor if you smoke or if you have or have ever had diabetes, an irregular heartbeat, hypertension (high blood pressure), high cholesterol, bleeding problems, or heart, kidney, or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, are breast-feeding, or if you plan on fathering a child. You should not become pregnant while you are taking ibrutinib. If you are female, you will need to take a pregnancy test before you start treatment and should use birth control to prevent pregnancy during your treatment with ibrutinib and for 1 month after you stop taking the medication. If you are male, you and your female partner should use birth control during your treatment with ibrutinib and continue for 1 month after your final dose. If you or your partner become pregnant while taking ibrutinib, call your doctor immediately. Ibrutinib can cause fetal harm.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking ibrutinib. Your doctor may tell you to stop taking ibrutinib 3 to 7 days before the surgery or procedure.

## What special dietary instructions should I follow?

Do not eat grapefruit or Seville oranges (sometimes used in marmalades), or drink grapefruit juice while taking this medication.

Make sure you drink plenty of water or other fluids every day while you are taking ibrutinib.

## **What should I do if I forget a dose?**

Take the missed dose as soon as you remember it that day. However, if you do not remember until the next day, 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?**

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

- diarrhea
- nausea
- constipation
- vomiting
- stomach pain
- heartburn or indigestion
- decreased appetite
- excessive tiredness or weakness
- muscle, bone, and joint pain
- muscle spasms
- swelling of the hands, feet, ankles, or lower legs
- rash
- itching
- sores in the mouth and throat
- anxiety
- difficulty falling asleep or staying asleep
- cough, runny or stuffed nose
- blurred vision
- dry or watery eyes
- pink eye

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- swelling of the face, throat, tongue, lips, and eyes
- difficulty swallowing or breathing

- hives
- unusual bruising or bleeding
- pink, red, or dark brown urine
- bloody or black, tarry stools
- nose bleeding
- bloody vomit; or vomiting blood or brown material that resembles coffee grounds
- seizures
- fast or irregular heartbeat
- shortness of breath
- chest discomfort
- dizziness, lightheadedness or feeling faint
- vision changes
- headache (that lasts a long time)
- fever, chills, cough, red, warm skin, or other signs of infection
- confusion
- changes in your speech
- decreased urination
- painful, frequent, or urgent urination

Ibrutinib may increase your risk of developing certain types of cancer including cancer of the skin or other organs. Talk to your doctor about the risks of taking ibrutinib.

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 light, excess heat and moisture not in the bathroom.

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.

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>]

## 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.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests and monitor your blood pressure to check your body's response to ibrutinib.

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

- Imbruvica®

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