

Ibrutinib (Imbruvica)

About This Medicine

Ibrutinib is used to treat cancer and chronic graft versus host disease (GVHD), a side effect from undergoing an allogeneic stem cell transplant. 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, and raise your risk of bleeding.
- 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.
- Bruising
- Nausea
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Tiredness
- Bone and muscle pain
- Muscle spasms
- Headache
- Fever
- Pneumonia
- Rash

Note: Each of the side effects above was reported in 20% or greater of patients treated with ibrutinib. 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 medical team.

Warnings and Precautions

- Severe abnormal bleeding, which can be life-threatening
- Severe bone marrow suppression



- Risk of severe and life-threatening infections
- Changes in your heart function such as life-threatening abnormal heartbeats, heart failure and sudden death have happened, especially in people who have an infection, an increased risk of heart disease and/or have had heart rhythm problems.
- High blood pressure
- This medicine may raise your risk of getting a second cancer, such as non-melanoma skin cancer.
- Tumor lysis syndrome: This medicine may act on the cancer cells very quickly. This may affect how your kidneys work.
- Changes in your liver function which can cause liver failure and 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

- You may need to hold ibrutinib for at least 3 to 7 days prior to and after surgical procedures due to the risk of bleeding. Talk to your doctor and/or nurse for precautions you may need to take. Also, if you must have emergency surgery, tell the doctor that you are on ibrutinib.

How to Take Your Medicine

- Swallow the medicine whole with a glass of water at the same time each day. Do not open, break, or chew the capsules. Do not cut, crush, or chew the tablets.
- For the oral suspension, follow the instructions given to you with the medicine.
- **Missed dose:** If you miss a dose, take it as soon as you think about it on that day. Do not take 2 doses at the same time and do not double up on the next dose.
- **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.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store the tablets and capsules in the original container at room temperature.
- Store the oral suspension at 36°F to 77°F (2°C to 25°C). Do not freeze. Do not use if the carton seal is broken or missing. Throw away any unused oral suspension within 60 days after first opening of the bottle.
- **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 nurse or your doctor how to dispose of unused medicine.

Treating Side Effects



- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your doctor's approval. 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 help 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.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). 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.
- 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 nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- 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.

Food and Medicine Interactions

- Avoid grapefruit products and Seville oranges while taking this medicine as it may raise the levels of ibrutinib in your body which could make side effects worse.
- 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 medicine interactions with ibrutinib. 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.
- 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 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
- A headache that does not go away
- Blurry vision or other changes in eyesight
- Tiredness and weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Wheezing and/or trouble breathing
- A cough that is bothersome
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your mouth or throat that makes it hard to eat or drink
- Pain in your abdomen that does not go away
- 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
- Swelling of the legs, feet, or ankles
- 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
- 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 infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures.
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine 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 1 month after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 month after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk. For this reason, women should not breastfeed during treatment and for 1 week after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.



- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan on having children. Ask for information on sperm or egg banking.

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