

imbruvica[®] (ibrutinib)

420, 280, 140 mg tablets | 140, 70 mg capsules
70 mg/mL oral suspension

Here's to starting with confidence



Please review the Important Side Effect Information throughout and on **pages 5-7**.
Please see the full Important Product Information at [imbruvica.com/prescribing-information](https://www.imbruvica.com/prescribing-information)

Here's to staying on track with treatment

Whether you are new to IMBRUVICA® (ibrutinib) or have been taking it for years, it's important to understand some of the common side effects you may experience.

Fortunately, many side effects can be managed with the help of your healthcare team. Your doctor can help you understand what to expect and how to address side effects if they occur.

Take IMBRUVICA® exactly as your doctor instructs.

IMBRUVICA® may cause serious side effects, including: bleeding problems (hemorrhage); infections; heart rhythm problems (ventricular arrhythmias, atrial fibrillation, and atrial flutter); heart failure and death; high blood pressure (hypertension); decrease in blood cell counts; second primary cancers; and tumor lysis syndrome (TLS).*

*TLS is a disorder caused by the fast breakdown of cancer cells, which can lead to kidney failure and other abnormalities.

The most common side effects of IMBRUVICA® in adults with B-cell malignancies (CLL/SLL and WM) include: diarrhea, tiredness, muscle and bone pain, rash, bruising, and nausea.

The most common side effects of IMBRUVICA® in adults or children 1 year of age and older with cGVHD include: tiredness, low red blood cell count (anemia), bruising, diarrhea, low platelet count, muscle and joint pain, fever, muscle spasms, mouth sores (stomatitis), bleeding, nausea, stomach pain, pneumonia, and headache.

These are not all the possible side effects of IMBRUVICA®. Please read the full Important Side Effect Information on **pages 5-7**.

Uses:

IMBRUVICA® (ibrutinib) is a prescription medicine used to treat:

- Adults with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with or without 17p deletion.
- Adults with Waldenström's macroglobulinemia (WM).
- Adults and children 1 year of age and older with chronic graft versus host disease (cGVHD) after failure of 1 or more lines of systemic therapy.

Helpful tips for managing certain side effects while taking IMBRUVICA® (ibrutinib)

People are all different—and so are their treatment experiences. The following suggestions may help you while on IMBRUVICA®.

To help when experiencing diarrhea:

- Stay hydrated. Drink fluids such as water, decaffeinated tea, and clear broth
- Eat small amounts of food that are easy to digest
- Avoid high-fat and high-fiber foods, raw fruits and vegetables, and foods that are very spicy
- Avoid alcohol and drinks with caffeine

Drink plenty of fluids during treatment with IMBRUVICA® to help reduce your risk of losing too much fluid (dehydration) due to diarrhea.

Tell your healthcare provider if you have diarrhea that does not go away.

Diarrhea is a common side effect in people who take IMBRUVICA®. In clinical trials, 43% of patients (497/1157) treated with IMBRUVICA® experienced diarrhea. Based on data from 1,605 patients from randomized controlled trials, the median* time to onset was 21 days (range, 0-708 days) and lasted a median of 7 days (range, 1-655 days). The diarrhea completely went away in 85% of those people.

*Median is the middle number in a group of numbers that are arranged from lowest to highest. For example, in the group of numbers 1-11, 6 is the median.

Learn more
about treatment
with IMBRUVICA®
by visiting
[IMBRUVICA.com](https://www.imbruvica.com)

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To help reduce tiredness:

- Balance periods of light movement with periods of rest
- Get plenty of sleep, which may include short naps
- Remain well hydrated throughout the day
- Eat a well-balanced diet



To help prevent infection:

- Wash hands often and bathe every day
- Avoid crowds and individuals with contagious diseases
- Do not keep fresh flowers or live plants in your bedroom
- Do not clean up droppings from your pets; have someone else do this for you

Infection is a serious possible side effect of IMBRUVICA® (ibrutinib). Notify a healthcare professional immediately if signs of infection occur, such as fever, chills, weakness, or confusion.

Changing your IMBRUVICA® dose to manage certain side effects

If you continue to experience side effects that are severe or persistent, be sure to discuss this with your healthcare team. Your doctor may consider a dose adjustment to manage certain side effects. This may include pausing or stopping IMBRUVICA®.



When Eddie experienced side effects with IMBRUVICA®, he talked to his doctor.

Learn more about Eddie's story at imbruvica.com/patientstories

IMPORTANT SIDE EFFECT INFORMATION

Before taking IMBRUVICA[®], tell your healthcare provider about all of your medical conditions, including if you:

- have had recent surgery or plan to have surgery. Your healthcare provider may stop IMBRUVICA[®] for any planned medical, surgical, or dental procedure.
- have bleeding problems
- have or had heart rhythm problems, smoke, or have a medical condition that increases your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes
- have an infection
- have liver problems
- are pregnant or plan to become pregnant. IMBRUVICA[®] can harm your unborn baby. If you are able to become pregnant, your healthcare provider will do a pregnancy test before starting treatment with IMBRUVICA[®]. Tell your healthcare provider if you are pregnant or think you may be pregnant during treatment with IMBRUVICA[®].
 - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with IMBRUVICA[®] and for 1 month after the last dose.
 - **Males** with female partners who are able to become pregnant should use effective birth control, such as condoms, during treatment with IMBRUVICA[®] and for 1 month after the last dose.
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with IMBRUVICA[®] and for 1 week after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking IMBRUVICA[®] with certain other medicines may affect how IMBRUVICA[®] works and can cause side effects.

How should I take IMBRUVICA[®]?

- Take IMBRUVICA[®] exactly as your healthcare provider tells you to take it.
- Take IMBRUVICA[®] 1 time a day at about the same time each day.

IMBRUVICA[®] comes as capsules, tablets, and oral suspension.

- **If your healthcare provider prescribes IMBRUVICA[®] capsules or tablets:**
 - Swallow IMBRUVICA[®] capsules or tablets whole with a glass of water.
 - Do not open, break, or chew IMBRUVICA[®] capsules.
 - Do not cut, crush, or chew IMBRUVICA[®] tablets.
- **If your healthcare provider prescribes IMBRUVICA[®] oral suspension:**
 - See the detailed Instructions for Use that comes with IMBRUVICA[®] oral suspension for information about the correct way to give a dose to your child. If you have questions about how to give IMBRUVICA[®] oral suspension, talk to your healthcare provider.
 - Do not use if the carton seal is broken or missing.

IMPORTANT SIDE EFFECT INFORMATION (continued)

- If you miss a dose of IMBRUVICA® take it as soon as you remember on the same day. Take your next dose of IMBRUVICA® at your regular time on the next day. Do not take extra doses of IMBRUVICA® to make up for a missed dose.
- If you take too much IMBRUVICA® call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking IMBRUVICA®?

- You should not drink grapefruit juice, eat grapefruit, or eat Seville oranges (often used in marmalades) during treatment with IMBRUVICA®. These products may increase the amount of IMBRUVICA® in your blood.

What are the possible side effects of IMBRUVICA®?

IMBRUVICA® may cause serious side effects, including:

- **Bleeding problems (hemorrhage) are common** during treatment with IMBRUVICA®, and can also be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs of bleeding, including: blood in your stools or black stools (looks like tar), pink or brown urine, unexpected bleeding, or bleeding that is severe or that you cannot control, vomit blood or vomit looks like coffee grounds, cough up blood or blood clots, increased bruising, dizziness, weakness, confusion, change in your speech, or a headache that lasts a long time or severe headache.
- **Infections** can happen during treatment with IMBRUVICA®. These infections can be serious and may lead to death. Tell your healthcare provider right away if you have fever, chills, weakness, confusion, or other signs or symptoms of an infection during treatment with IMBRUVICA®.
- **Heart problems.** Serious heart rhythm problems (ventricular arrhythmias, atrial fibrillation and atrial flutter), heart failure and death have happened in people treated with IMBRUVICA®, especially in people who have an infection, an increased risk for heart disease, or have had heart rhythm problems in the past. Your heart function will be checked before and during treatment with IMBRUVICA®. Tell your healthcare provider if you get any symptoms of heart problems, such as feeling as if your heart is beating fast and irregular, lightheadedness, dizziness, shortness of breath, swelling of the feet, ankles or legs, chest discomfort, or you faint. If you develop any of these symptoms, your healthcare provider may do tests to check your heart and may change your IMBRUVICA® dose.
- **High blood pressure (hypertension).** New or worsening high blood pressure has happened in people treated with IMBRUVICA®. Your healthcare provider may start you on blood pressure medicine or change current medicines to treat your blood pressure.
- **Decrease in blood cell counts.** Decreased blood counts (white blood cells, platelets, and red blood cells) are common with IMBRUVICA®, but can also be severe. Your healthcare provider should do monthly blood tests to check your blood counts.
- **Second primary cancers.** New cancers have happened during treatment with IMBRUVICA®, including cancers of the skin or other organs.

- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your healthcare provider may do blood tests to check you for TLS.

The most common side effects of IMBRUVICA® in adults with B-cell malignancies (CLL/SLL and WM) include:

- diarrhea
- muscle and bone pain
- bruising
- tiredness
- rash
- nausea

The most common side effects of IMBRUVICA® in adults or children 1 year of age and older with cGVHD include:

- tiredness
- muscle and joint pain
- nausea
- low red blood cell count (anemia)
- fever
- stomach pain
- bruising
- muscle spasms
- pneumonia
- diarrhea
- mouth sores (stomatitis)
- headache
- low platelet count
- bleeding

Diarrhea is a common side effect in people who take IMBRUVICA®. Drink plenty of fluids during treatment with IMBRUVICA® to help reduce your risk of losing too much fluid (dehydration) due to diarrhea. Tell your healthcare provider if you have diarrhea that does not go away.

These are not all the possible side effects of IMBRUVICA®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMBRUVICA®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use IMBRUVICA® for a condition for which it was not prescribed. Do not give IMBRUVICA® to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about IMBRUVICA® that is written for health professionals.

Please see the full Important Product Information at imbruvica.com/prescribing-information

USES

What is IMBRUVICA® (ibrutinib)?

IMBRUVICA® (ibrutinib) is a prescription medicine used to treat:

- Adults with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL).
- Adults with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion.
- Adults with Waldenström’s macroglobulinemia (WM).
- Adults and children 1 year of age and older with chronic graft versus host disease (cGVHD) after failure of 1 or more lines of systemic therapy.

It is not known if IMBRUVICA® is safe and effective in children under 1 year of age.



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Talk with your healthcare team

It's important to discuss any concerns you have with your IMBRUVICA[®] treatment—including side effects that persist or worsen.

From the moment you're prescribed IMBRUVICA[®], IMBRUVICA[®] By Your Side provides resources and support for getting the help you may need during treatment.



To learn more about IMBRUVICA[®] By Your Side, call **1-888-YourSide** (1-888-968-7743) Monday-Friday, 8:00 AM - 8:00 PM ET or visit imbruvicaByYourSide.com

IMBRUVICA[®] By Your Side patient support program is not intended to provide medical advice, replace prescribed treatment plans, or provide treatment or case management services. Patients are advised to talk to their healthcare provider and treatment team about any medical decisions and concerns they may have.



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