# UNDERSTANDING SEVERAL SIDE EFFECTS

## Helpful tips for patients on IMBRUVICA® (ibrutinib)

### You may experience side effects while taking IMBRUVICA®[1]

We are all different and react differently to treatment. The suggestions below may help you while on IMBRUVICA®. Talk to your healthcare provider if you think you are experiencing any side effects.

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). Please see Important Side Effect Information on pages 2 and 3. Talk to your healthcare provider if you think you are experiencing side effects.

**To help with upset stomach, nausea, or diarrhea[2-4]:**

- Hydrate with fluids such as water, apple juice, ginger ale, warm or lukewarm tea, or clear broth
- Avoid consumption of spicy, fatty, and/or greasy foods
- Eat bland foods such as crackers or dry toast
- Consider the **BRAT** diet during periods of diarrhea: **B**ananas, **R**ice, **A**pplesauce, **T**oast

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) and lasted a median of 7 days (range, 1-655). The diarrhea completely went away in 85% of those people.[1]

*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.

**To help reduce tiredness[5]:**

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

**To help prevent infection[6]:**

- Wash hands often and bathe every day
- Avoid crowds and individuals with contagious diseases
- Drink plenty of fluids
- Talk to your doctor or nurse if you are planning any travel during this time

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

### IMPORTANT SIDE EFFECT INFORMATION

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).

**These are not all the possible side effects. Please see the Important Side Effects Information on the following page.**

**The information in this handout is not intended to replace the advice of your doctor. If you have any questions about your IMBRUVICA® treatment, be sure to contact your healthcare provider.**

Please see the Important Side Effects Information on the following pages and click here for full Important Product Information.

imbruvica®
(ibrutinib)
420, 280, 140 mg tablets | 140, 70 mg capsules
70 mg/mL oral suspension

# Talk with your doctor about any side effects that you experience while taking IMBRUVICA® (ibrutinib).

**The results seen in clinical studies are based on patients taking IMBRUVICA® every day, as directed by their doctor.**

**Establish a routine to help you remember to take your medicine.**

**Set an alarm, or pair IMBRUVICA® with an activity that you do every day.**

## How to 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.
- 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.

## 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.

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# Talk with your doctor about any side effects that you experience while taking IMBRUVICA® (ibrutinib).

## IMPORTANT SIDE EFFECT INFORMATION (continued)

### 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.
- 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
- tiredness
- muscle and bone pain
- rash
- bruising
- nausea

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# Talk with your doctor about any side effects that you experience while taking IMBRUVICA® (ibrutinib).

## IMPORTANT SIDE EFFECT INFORMATION (continued)

**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
- headache

**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.

## 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.

**Please click here for full Important Product Information.**

imbruvica® By Your Side™ Patient Support

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

**References: 1.** IMBRUVICA® (ibrutinib) Prescribing Information. **2.** American Cancer Society. Managing Nausea and Vomiting at Home. https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/nausea-and-vomiting/nausea-and-vomiting.html. Updated September 2020. Accessed January 7, 2021. **3.** Shaw C, Taylor L. Treatment-related diarrhea in patients with cancer. Clin J Oncol Nurs. 2012;16(4):413-417. **4.** National Cancer Institute. Diarrhea and Cancer Treatment. http://www.cancer.gov/cancertopics/coping/chemo-side-effects/diarrhea.pdf. Updated August 2018. Accessed January 7, 2021. **5.** American Cancer Society. https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/fatigue/managing-cancer-related-fatigue.html. Updated February 2020. Accessed January 7, 2021. **6.** American Cancer Society. Infections in People with Cancer. American Cancer Society. https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/low-blood-counts/infections/preventing-infections-in-people-with-cancer.html. Updated April 2020. Accessed January 7, 2021.

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