

# UNDERSTANDING SEVERAL SIDE EFFECTS

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

### You may experience side effects while taking IMBRUVICA®<sup>1</sup>

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, decrease in blood cell counts, heart rhythm problems (ventricular arrhythmias, atrial fibrillation and atrial flutter) and heart failure, high blood pressure (hypertension), second primary cancers, and tumor lysis syndrome (TLS). Please see Important Side Effect Information on page 2. Talk to your healthcare provider if you think you are experiencing side effects.



#### To help with upset stomach, nausea, or diarrhea<sup>2-4</sup>:

- 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.<sup>1</sup>

\*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<sup>5</sup>:

- 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<sup>6</sup>:

- 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, decrease in blood cell counts, heart rhythm problems (ventricular arrhythmias, atrial fibrillation and atrial flutter) and heart failure, high blood pressure (hypertension), 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.**

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®

Depending on the specific condition, IMBRUVICA® is dosed once a day as either a single tablet or three or four capsules. Talk to your doctor about which dosing option is right for you.

Swallow the tablet or capsules whole with a glass of water at about the same time each day.

Do not open, break, or chew the capsules.

Do not cut, crush, or chew the tablets.

Take IMBRUVICA® as prescribed by your doctor. Do not change or skip your dose without talking to your healthcare provider first.

**imbruvica®**  
**(ibrutinib)**

560, 420, 280, 140 mg tablets | 140, 70 mg capsules

Please review the reverse side for additional Important Side Effect Information and review the accompanying full Important Product Information.

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

## 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.
- 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.
- Take IMBRUVICA® at about the same time each day.
- 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®.
- **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.

- **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 increased risk for heart disease, have an infection, or who have had heart rhythm problems in the past. 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 a test to check your heart (ECG) 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.
- **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 (MCL, CLL/SLL, WM and MZL) include:

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

The most common side effects of IMBRUVICA® in adults with cGVHD include:

- tiredness
- mouth sores (stomatitis)
- nausea
- diarrhea
- muscle spasms
- pneumonia

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:

- Mantle cell lymphoma (MCL) who have received at least one prior treatment
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)
- Marginal zone lymphoma (MZL) who require a medicine by mouth or injection (systemic therapy) and have received a certain type of prior treatment
- 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.

Please see the accompanying 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](http://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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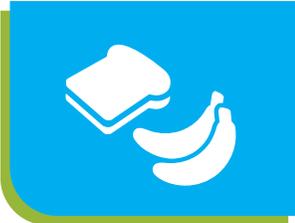
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#### To help with upset stomach, nausea, or diarrhea<sup>2-4</sup>:

- Hydrate with fluids such as water, apple juice, ginger ale, warm or lukewarm tea, or clear broth
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Establish a routine to help you remember to take your medicine.



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For more resources to help build a routine with IMBRUVICA®, [click here](#).

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*continued on next page*

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

## IMPORTANT SIDE EFFECT INFORMATION (continued)

### What are the possible side effects of IMBRUVICA®? (continued)

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

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

### The most common side effects of IMBRUVICA® in adults with cGVHD include:

- tiredness
- mouth sores (stomatitis)
- muscle spasms
- bruising
- nausea
- diarrhea
- pneumonia

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