

Talking to Your Doctor About Side Effects

➤ Everyone's experience with IMBRUVICA® (ibrutinib) may be different. Most people may experience side effects while taking IMBRUVICA®. **It is important to talk with your doctor and healthcare team about how you are feeling.** You can report side effects to the FDA by calling 1-800-FDA-1088.

Use this worksheet to learn some tips about managing some of the more common side effects of IMBRUVICA®. Remember to keep track of the ones you experience and talk to your doctor about them.



Side Effect: Diarrhea and Nausea

If you have diarrhea or nausea, try to

- ✓ Drink clear fluids like water, broth, or apple juice to stay hydrated
- ✓ Eat bland or mild foods, like those on the BRAT diet (bananas, rice, applesauce, toast)
- ✓ Avoid spicy, greasy, or fatty foods and limit drinks with caffeine or alcohol
- ✓ Eat frequent small meals throughout the day rather than fewer large meals



Side Effect: Tiredness (Fatigue)

If you have fatigue, try to

- ✓ Strike a balance of activity and rest—know your limits and plan ahead
- ✓ Get plenty of sleep, which may include short naps
- ✓ Eat a well-balanced diet that includes protein
- ✓ Ask your doctor about physical activities that are safe for you and could help you keep your energy up

Please see the Important Side Effect Information on the following pages.

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Side Effect: Infection

If your white blood cell count lowers, your immune system can have a harder time fighting germs, which can lead to infections.

To help lower your risk for infections, try to

- ✓ Wash your hands regularly with soap and warm water, and encourage those around you to wash their hands, too
- ✓ Stay away from people who are sick and avoid large crowds if possible
- ✓ Clean and disinfect surfaces you touch such as doorknobs, countertops, or phones

Keep Track of Your Side Effects

Whether you experience any of these side effects or others, **it's important to tell your doctor about them.** One way to keep track of side effects is to write down how you feel day-to-day. Try taking some notes each day and bringing them with you to your next appointment.

Try this quick guide for tracking. You can write your responses to these questions in a journal or on a calendar. Download tracking calendar pages at www.youandisupport.com/resources.

What was the symptom or side effect? _____

When did you feel it? _____

How long did it last? _____

How would you rate it (1-10)? _____

Please see the Important Side Effect Information on the following pages.

IMPORTANT SIDE EFFECT INFORMATION

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.

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®.
 - **Females** should not become pregnant during treatment and for 1 month after the last dose of IMBRUVICA®.
 - **Males** should avoid getting female partners pregnant during treatment and for 1 month after the last dose of IMBRUVICA®.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take IMBRUVICA® or breastfeed.

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 and 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.

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.
- **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 rhythm problems (ventricular arrhythmias, atrial fibrillation and atrial flutter).** Serious heart rhythm problems 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 rhythm problems, such as feeling as if your heart is beating fast and irregular, lightheadedness, dizziness, shortness of breath, 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.

IMPORTANT SIDE EFFECT INFORMATION CONTINUED

- **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
- bruising
- nausea
- tiredness
- fever

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

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

Please see the full Important Product Information on www.imbruvica.com.

