What is IMBRUVICA® (ibrutinib)?

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

- Waldenström’s macroglobulinemia (WM)

It is not known if IMBRUVICA® is safe and effective in children.

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), high blood pressure (hypertension), second primary cancers, and tumor lysis syndrome (TLS).

Please review the Important Side Effect Information on pages 6 and 7. Please see the accompanying full Important Product Information.
Welcome to a different way of treating WM

Starting treatment is an important time. This brochure will help you learn about your disease and how IMBRUVICA® may be able to help you on your journey.

Researchers continue to learn more about how changes in blood cells occur in Waldenström’s macroglobulinemia (WM). These discoveries are helping them develop oral medications such as IMBRUVICA®.

IMBRUVICA® works differently than other treatments such as chemotherapy. For more information on how IMBRUVICA® works, turn to page 4 of this brochure.

With once-daily IMBRUVICA®, you now have an oral treatment option that doesn’t require chemotherapy.

IMBRUVICA® is a prescription medicine used to treat adults with WM. It is not known if IMBRUVICA® is safe and effective in children.

IMPORTANT SIDE EFFECT INFORMATION (CON’T)

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)
- High blood pressure (hypertension)
- Second primary cancers
- Tumor lysis syndrome (TLS)

The information in this brochure 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 team.

Understanding WM

Everyone reacts to the news that they have cancer in their own way. It’s normal to feel overwhelmed emotionally and physically. Learning about WM can help you feel more at ease.

WM is a rare type of lymphoma that usually progresses slowly. B cells are a type of white blood cell. They are an important part of your immune system—your body’s defense against infection. In WM, abnormal B cells grow out of control and may crowd out healthy cells in your bone marrow (the soft inner part of bones responsible for making blood cells), lymph nodes (small glands containing immune cells that fight infection), and other organs. The abnormal B cells can also release large amounts of a certain type of antibody (immunoglobulin M, or IgM).

When this happens, you are more likely to get infections and experience other symptoms mentioned below.

Common symptoms of WM may include:

- Fever
- Night sweats
- Weight loss
- Peripheral neuropathy (numbness or a painful “pins and needles” sensation in the feet, legs, and hands)
- Hyperviscosity (an increase in the thickness of the blood which may lead to abnormal bleeding from the nose, gums, GI tract, fatigue, and blurred vision).

How you feel matters

Only you know how you are feeling. If you’re feeling mentally or physically tired, for example, it’s important to speak up and tell your doctor.

IMPORTANT SIDE EFFECT INFORMATION (CON’T)

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.

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IMBRUVICA® (ibrutinib) has helped people with WM

- In a trial of 63 patients with previously treated WM, 62% (39 patients) had a response to IMBRUVICA®, which means that their doctor observed fewer signs of the disease as seen through blood tests, X-rays, CT scans, and/or bone marrow tests.
- Of the patients who responded, the median time to respond to IMBRUVICA® treatment was 1.2 months.

*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.

IMBRUVICA® is an oral, once-daily WM medication that works differently than chemotherapy

- IMBRUVICA® blocks a protein in B cells called Bruton’s tyrosine kinase, or BTK. BTK signaling is involved in abnormal B-cell multiplication and survival.
- By blocking BTK, IMBRUVICA® may help move abnormal B cells out of their nourishing environments in the lymph nodes, bone marrow, and other organs.
- It’s important that you take IMBRUVICA® every day as prescribed by your doctor to manage your disease.

Because of how IMBRUVICA® works, it may cause side effects.

IMPORTANT SIDE EFFECT INFORMATION (CON’T)

IMBRUVICA® may cause serious side effects, including:

- 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.
- 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.
- 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.

IMBRUVICA® is the only FDA-approved treatment for WM. Please talk to your doctor about whether IMBRUVICA® is right for you.

Please review the Important Side Effect Information on pages 6 and 7. Please see the accompanying full Important Product Information.
Take IMBRUVICA® at about the same time each day.

Waldenstrom’s macroglobulinemia (WM)

It is not known if IMBRUVICA® is safe and effective in children.

What is IMBRUVICA® (ibrutinib)?

If you take too much IMBRUVICA®, call your healthcare provider or go to the nearest hospital emergency room right away.

Do not cut, crush, or chew IMBRUVICA® tablets.

Do not open, break, or chew IMBRUVICA® capsules.

Take IMBRUVICA® exactly as your healthcare provider tells you to take it.

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.

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.

- 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.

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.

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
- nausea

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

- mouth sores (stomatitis)
- muscle spasms
- pneumonia

Diabetes 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 accompanying full Important Product Information.

References:


What you should know about the side effects of IMBRUVICA® (ibrutinib)

**IMBRUVICA®** can cause serious side effects, including:

- Bleeding problems (hemorrhage)
- Infections
- Decrease in blood cell counts
- Heart rhythm problems (ventricular arrhythmias, atrial fibrillation and atrial flutter)

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

In the clinical trial, 6% of WM patients stopped taking IMBRUVICA® because of side effects.4

This is not a complete list of side effects. Others may occur.
Tell your doctor if you think you are experiencing side effects.

Tips to help with diarrhea

- Stay hydrated. Drink fluids such as water, decaffeinated tea, and clear broth.5
- Eat small meals often, and avoid very hot or spicy foods.5
- Avoid greasy foods, bran, raw fruits and vegetables, caffeine, alcohol, and tobacco.5

**IMPORTANT SIDE EFFECT INFORMATION (CON’T)**

The most common side effects in the clinical trial were:

- Low white blood cell count
- Low blood platelet count
- Diarrhea
- Rash

- Nausea
- Muscle spasms
- Fatigue (tiredness)

In the clinical trial, 6% of WM patients stopped taking IMBRUVICA® because of side effects.4

This is not a complete list of side effects. Others may occur.
Tell your doctor if you think you are experiencing side effects.

**IMPORTANT SIDE EFFECT INFORMATION (CON’T)**

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 review the Important Side Effect Information on pages 6 and 7.
Please see the accompanying full Important Product Information.
You can take IMBRUVICA® (ibrutinib) anywhere

Because IMBRUVICA® is an oral medication, you have the freedom to take it at home or wherever you may be. It’s important to continue to take your medication at about the same time each day, and exactly as directed by your doctor.3

• Take all IMBRUVICA® pills by mouth, at about the same time each day, with a glass of water.
• Swallow the pills whole. Do not open, break, cut, crush, or chew the pills.
• Please talk to your doctor if you consider any changes in your treatment.
• Remember to refill your IMBRUVICA® prescription before running out.
• 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.
  ✦ Call your doctor or pharmacist if you have any questions.
• Tell your doctor about any other medications you are taking, including prescriptions or over-the-counter medications, vitamins, and herbal supplements. Taking IMBRUVICA® with certain other medicines may affect how IMBRUVICA® works and can cause side effects.
• Store IMBRUVICA® in its original container at room temperature from 68°F to 77°F (20°C to 25°C).

While taking IMBRUVICA®

• Do not drink grapefruit juice.
• Do not eat grapefruit.
• Do not eat Seville oranges, often used in marmalade.
These products may increase the amount of IMBRUVICA® in your blood.

How to create your new treatment routine

Creating a routine will help you remember to take all doses of your medicine as directed by your doctor, so you get the most benefit out of your treatment.6,7

• Pair IMBRUVICA® with an activity that you do every day, like reading a book at bedtime
• Keep a calendar or journal, such as the one in the IMBRUVICA® Patient Starter Kit, where you can use stickers to check off each day you take your medication
• Add an alarm to help you remember to take your medication
• Send reminder alerts to your phone by using the free Care4Today® Connect Mobile Health Manager app. Visit www.care4today.com to download the app on your phone
• Ask a family member or friend to remind you when it’s time to take IMBRUVICA®

Care4Today is a registered trademark of Johnson & Johnson Corporation.

Please review the Important Side Effect Information on pages 6 and 7. Please see the accompanying full Important Product Information.
Discover a World of Support

We know that understanding insurance coverage and affording your medication come with challenges—that’s why we’re committed to providing you with personalized support: access, affordability support options, and nurse call support and resources.

Access Support
We offer one-on-one support to help you learn about access to IMBRUVICA® (ibrutinib) by helping you understand your insurance coverage.

Affordability Support Options
Regardless of insurance type, we can help you understand your options.

For patients with commercial insurance
• YOU&i™ Instant Savings Program: If you are eligible and have commercial health insurance, you pay no more than $10 per prescription* for IMBRUVICA®

For patients with federally funded Medicare, Medicaid, or commercial insurance
• Foundation information: If you need additional financial support, we can provide you with information on independent foundations that may be able to help. Independent copay assistance foundations have their own rules for eligibility. We have no control over these independent foundations.

Other Resources
Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF) provides free prescription medications to eligible individuals without insurance coverage for their medicines and those who do not have adequate financial resources to pay for them. To see if you might qualify for assistance, please contact a JJPAF program specialist at 1-800-652-6227 (9:00 AM to 6:00 PM ET) or visit the foundation website at www.JJPAF.org.

Nurse Call Support and Resources
Our YOU&i™ nurses and resources may be able to answer your questions about IMBRUVICA® and your disease.
• Ongoing calls with your YOU&i™ nurse scheduled at a time convenient for you
• Ongoing educational materials sent to your email or home address
• Patient Starter Kits for new IMBRUVICA® patients

Enroll in the YOU&i™ Support Program today

Call 1-877-877-3536  www.youandisupport.com
Monday - Friday, 8 AM - 8 PM ET

YOU&i™ Support Program

YOU&i™ INSTANT SAVINGS PROGRAM

If you have commercial insurance you pay no more than $10 per prescription* for IMBRUVICA®

*Eligible patients may qualify for $10 per prescription of IMBRUVICA® until the maximum limit of $24,600 per calendar year is reached. The Instant Savings Program applies to commercial insurance co-pay, deductible, and coinsurance medication costs for IMBRUVICA®. This program cannot be used with any other federally-funded prescription insurance plan which includes Medicare Part D, Medicare Advantage Plan, Medicaid, TRICARE, or any other federal or state health care plan, including pharmaceutical assistance programs.

Enroll in the
YOU&i™ Support Program today

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Stay motivated
You are not alone. Surround yourself with friends, family, and support groups in order to stay motivated. One-on-one peer support programs, such as the Lymphoma Support Network (www.lymphoma.org), match lymphoma survivors and caregivers with volunteers who have gone through similar experiences.

Your family and friends may want to support you, but they might not know how. Make sure to tell them exactly how they can help. You might ask a friend or family member to:
- Be with you at doctor appointments
- Go grocery shopping for you or with you
- Do something fun to help you stay positive

Stay informed
Knowledge is empowering—so try to learn all you can about your condition. The websites below are a good place to find additional information on WM, treatment options, support groups, and resources:

For more information on WM
American Cancer Society  www.cancer.org
Leukemia & Lymphoma Society  www.lls.org
Lymphoma Research Foundation  www.lymphoma.org
International Waldenström’s Macroglobulinemia Foundation  www.iwmf.com

For cancer support communities
The Advocacy Connector  www.advocacyconnector.com
CancerCare  www.cancercare.org
Cancer Support Community  www.cancersupportcommunity.org
National Comprehensive Cancer Network (NCCN)  www.nccn.org/patients
Patient Advocate Foundation  www.patientadvocate.org

Remember, you are the most important person on your healthcare team. Staying informed and motivated will help you advocate for your own care.
IMBRUVICA® (ibrutinib)
560, 420, 280, 140 mg tablets | 70 mg capsules

To learn more, visit www.IMBRUVICA.com/WMinfo or call 1-877-877-3536

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