CLL
SLL

PATIENT GUIDE

What is IMBRUVICA® (ibrutinib)?

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

- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion

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 CLL/SLL

Starting treatment is an important time. This brochure will help you learn about your condition and how IMBRUVICA® (ibrutinib) can help you on your journey.

Researchers continue to learn more about how changes in blood cells occur in chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL). These discoveries are helping them develop oral medications such as IMBRUVICA®.[1]

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

With IMBRUVICA®, there's a once-daily oral treatment option available to treat CLL/SLL

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

- Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)
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It is not known if IMBRUVICA® is safe and effective in children.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

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)

imbruvica®
(ibrutinib)
560, 420, 280, 140 mg tablets | 140, 70 mg capsules

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 CLL/SLL

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

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 CLL, abnormal B cells grow out of control and may crowd out healthy cells in the ***lymph nodes*** (small glands containing immune cells that fight infection), ***bone marrow*** (the soft inner part of bones responsible for making blood cells), and other organs. When this happens, you are more likely to get infections and experience other symptoms mentioned below.[2,3]

What is the difference between CLL and SLL?

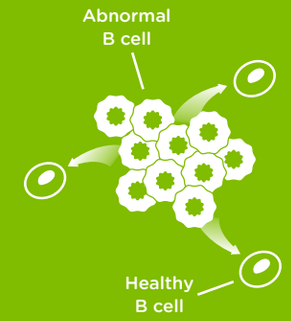
The main difference is where the cancer cells are found. In CLL, most of the cancer cells are in the blood and bone marrow. In SLL, the cancer cells are mainly in the lymph nodes.[4]

Common symptoms of CLL may include[2,3]:

- Enlarged lymph nodes
- Fever
- Night sweats
- Unexpected weight loss
- Frequent infections
- Abdominal pain or fullness
- Tiredness
- Easy bruising and bleeding

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.



In CLL, the abnormal B cells crowd out healthy B cells.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

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 many people with CLL/SLL live longer

More people treated with single-agent IMBRUVICA® in clinical trials lived longer than those taking another approved therapy.

In a clinical trial of 269 people with CLL who had not yet received any prior therapy[5]:

- Patients treated with IMBRUVICA® were **84%** less likely to have their disease worsen or die during the trial compared to another approved CLL therapy
- Patients treated with IMBRUVICA® were **56%** less likely to die during this trial compared to another approved CLL therapy

In a clinical trial of 391 previously treated people with CLL or SLL[5]:

- Patients treated with IMBRUVICA® were **78%** less likely to have their disease worsen or die during the trial compared to another approved CLL therapy
- Patients treated with IMBRUVICA® were **57%** less likely to die during this trial compared to another approved CLL therapy

IMBRUVICA® is an oral, once-daily CLL/SLL medication that works differently than chemotherapy

- IMBRUVICA® blocks a protein in B cells called Bruton's tyrosine kinase, or ***BTK***. BTK signaling is needed for abnormal B cells to multiply and survive[5]
- By blocking BTK, IMBRUVICA® may help move abnormal B cells out of their nourishing environments in the bone marrow, lymph nodes, and other organs[5]
- It's important that you take IMBRUVICA® every day as prescribed by your doctor to manage your disease
- IMBRUVICA® may slow the spread of CLL or SLL[5,6]

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

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

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.

Please review the Important Side Effect Information on pages 6 and 7.
Please see the accompanying full Important Product Information.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

IMBRUVICA® may cause serious side effects, including:

- **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.

IMPORTANT SIDE EFFECT INFORMATION

What is IMBRUVICA® (ibrutinib)?

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

- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion

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.
- 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.
- **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
- nausea
- bruising
- 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 accompanying full Important Product Information.

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References: 1. American Cancer Society. What's new in chronic lymphocytic leukemia research and treatment? http://www.cancer.org/cancer/leukemia-chroniclymphocyticcll/detailedguide/leukemia-chronic-lymphocytic-new-research. Accessed April 4, 2018. **2.** Leukemia & Lymphoma Society. Chronic lymphocytic leukemia. https://www.lls.org/content/nationalcontent/resourcecenter/freeeducationmaterials/leukemia/pdf/cll.pdf. Accessed April 4, 2018. **3.** American Cancer Society. Chronic lymphocytic leukemia. http://www.cancer.org/acs/groups/cid/documents/webcontent/003111-pdf.pdf. Accessed April 4, 2018. **4.** Lymphoma Research Foundation. Getting the facts. https://www.lymphoma.org/wp-content/uploads/2017/06/LRF_FACTSHEET_CLL_SLL.pdf. Accessed April 4, 2018. **5.** IMBRUVICA® (ibrutinib) Prescribing Information. Pharmacyclics LLC. 2018. **6.** Advani RH, Buggy JJ, Sharman JP, et al. Bruton tyrosine kinase inhibitor ibrutinib (PCI-32765) has significant activity in patients with relapsed/refractory B-cell malignancies. *J Clin Oncol*. 2013;31(1):88-94. **7.** American Cancer Society. Diarrhea. https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/getting-help-for-diarrhea-english.pdf. Accessed April 4, 2018. **8.** Cheson BD, Byrd JC, Rai KR, et al. Novel targeted agents and the need to refine clinical end points in chronic lymphocytic leukemia. *J Clin Oncol*. 2012;30(23):2820-2822. **9.** MedlinePlus. Taking medicine at home: create a routine. https://medlineplus.gov/ency/patientinstructions/000613.htm. Accessed April 4, 2018. **10.** Rolnick SJ, Asche S, Pawloski PA, Bruzek RJ, Hedblom B. Barriers to and facilitators of medication and adherence. *Am J Pharm Benefits*. 2013;5(5):209-215.

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

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

The most common side effects in the clinical trials were:

- Low white blood cell count
- Low blood platelet count
- Low red blood cell count
- Diarrhea
- Muscle and bone pain
- Nausea
- Rash
- Bruising
- Fatigue (tiredness)
- Fever
- Bleeding

In the clinical trials, approximately 4%-10% of CLL or SLL patients stopped taking IMBRUVICA® because of side effects.

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.[7]
- Eat small meals often, and avoid very hot or spicy foods.[7]
- Avoid greasy foods, bran, raw fruits and vegetables, caffeine, alcohol, and tobacco.[7]

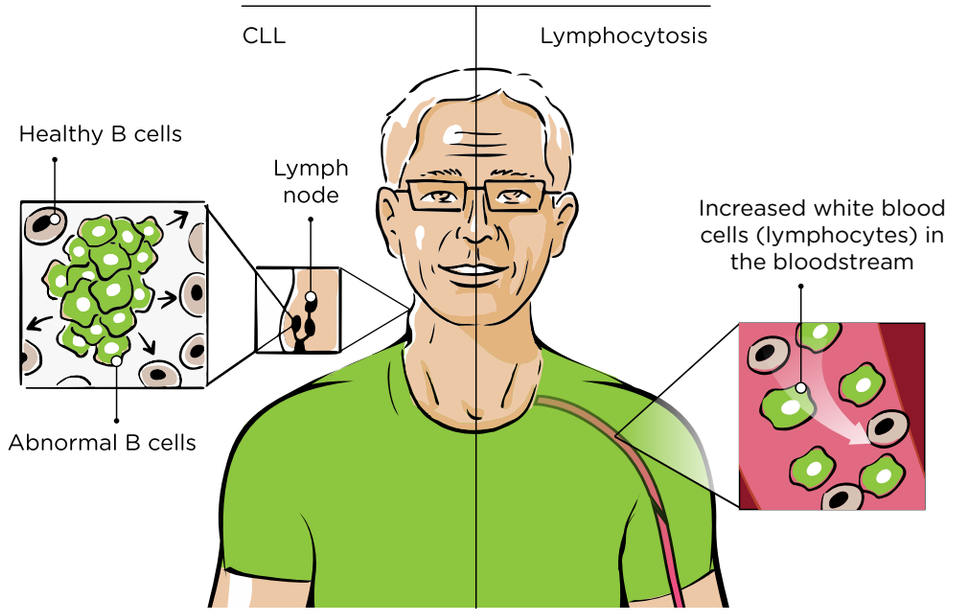
IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

The most common side effects of IMBRUVICA® include: diarrhea, muscle and bone pain, rash, nausea, bruising, tiredness, and fever.

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.

You may experience changes in your white blood cell count

After starting IMBRUVICA®, your doctor will monitor your blood cell counts. Your lab results may show an increase in lymphocytes, a type of white blood cell. This is called ***lymphocytosis*** and can occur with IMBRUVICA® treatment.[5] In the absence of other signs and symptoms, this increase may not necessarily mean your condition is worsening.[8]



In 3 clinical trials, 66% of people with CLL developed lymphocytosis. This typically occurred during their first month of IMBRUVICA® therapy and resolved by a median* of 14 weeks (0.1 to 104).[5]

*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.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

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.[5]

CLL/SLL

420 mg

DOSE SHOULD BE TAKEN AT ABOUT THE SAME TIME EACH DAY

- Take all IMBRUVICA® pills by mouth, at about the same time each day, with a glass of water.
  - If your doctor prescribed IMBRUVICA® in combination with bendamustine and rituximab (BR), continue to take IMBRUVICA® pills daily as directed during and after chemotherapy.
- 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.[9,10]

- 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.

YOU&i™ Support Program

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®

YOU&i™ INSTANT SAVINGS PROGRAM

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

*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.

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

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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 CLL/SLL, treatment options, support groups, and resources:

For more information on CLL/SLL

American Cancer Society	www.cancer.org
Leukemia & Lymphoma Society	www.lls.org
Lymphoma Research Foundation	www.lymphoma.org

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

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Remember, you are the most important person on your healthcare team. Staying informed and motivated will help you advocate for your own care.

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

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