

I am living with cGVHD
I am focusing on me

I am **IMBRUVICA**®

imbruvica®
(ibrutinib)

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

cGVHD=chronic graft versus host disease.

What is IMBRUVICA® (ibrutinib)?

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

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, tumor lysis syndrome (TLS), and fetal harm.

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

A guide to IMBRUVICA® (ibrutinib) and cGVHD

This brochure will help you learn about your condition and how IMBRUVICA® may be able to help you on your journey.

Contents include:

- An overview of cGVHD
- What to expect with cGVHD
- Treatment options
- Tips to help you manage your condition
- Guidelines for taking IMBRUVICA®
- Ways to find support

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.

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(ibrutinib)

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

cGVHD=chronic graft versus host disease.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

- **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®.

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

Understanding cGVHD

When you have been diagnosed with cGVHD, it's normal to feel overwhelmed emotionally and physically. Each cGVHD journey is different, so learning about why your body is reacting the way it is can help you feel more at ease. By focusing on what you can control, you and your caregiver can better manage your symptoms.

What is cGVHD?

Graft versus host disease (**GVHD**) is a common complication after receiving a stem cell donor transplant. Sometimes, the **graft** (transplanted cells) doesn't recognize the **host** (your body) as being friendly. In fact, it sees your body as a **"threat."**¹

There are two kinds of GVHD that may develop:

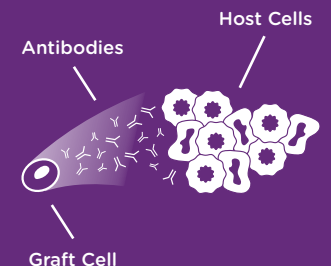
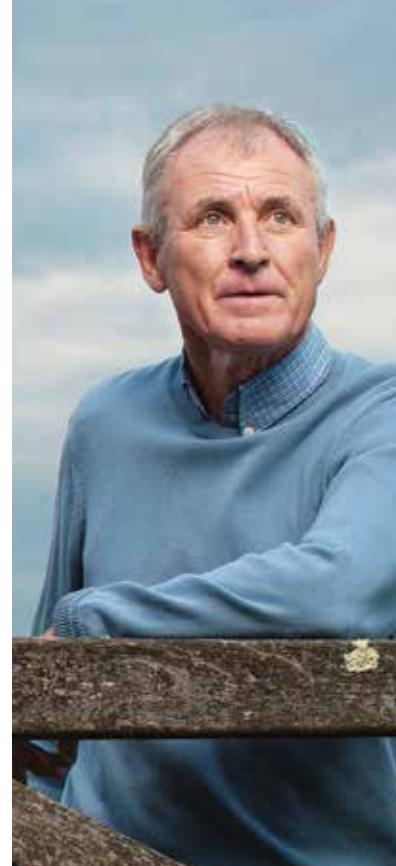
- Acute (*typically happens earlier after transplant*)
- Chronic (*typically occurs later after transplant*)

These two forms of GVHD differ in symptoms, treatment, and time of onset. This patient guide focuses on the chronic form of GVHD.²

Acute GVHD and chronic GVHD affect one or more organ systems, and they can continue over a long period of time. Unfortunately, cGVHD may occur after receiving a donor stem cell or bone marrow transplant.^{1,2}

The role your immune system plays

When your **immune system** is working normally, it helps defend your body against harmful invaders like viruses or bacteria. This helps you stay healthy. GVHD occurs when the graft perceives your own tissues as unfamiliar cells that should be destroyed.^{1,2}



In cGVHD, the graft (transplant) cells attack the host (your body) cells using the immune system²

Understanding symptoms

In cGVHD, your symptoms could last months or even years. Your symptoms could affect many different areas of the body. Some symptoms may be mild, others could be moderate or severe.^{2,3}

Common symptoms you may notice^{2,4}:

- Rash/skin changes
- Dry eyes
- Dry mouth
- Fatigue (feeling tired)
- Joint stiffness
- Change in skin color
- Difficulty breathing

No two patients are alike, so be sure to tell your doctor how you are feeling and if you are experiencing any new symptoms.

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.

How is cGVHD treated?

When considering your cGVHD treatment, your doctor will look at how severe your symptoms are. The **severity** of cGVHD depends on two things²:

- How much of your body is affected by the disease
- How much the disease interferes with your body's ability to function

People with **mild** forms of cGVHD can sometimes treat the disease locally with topical or combination therapy.²

Those with more **moderate to severe** forms of cGVHD may require **systemic** (throughout the body) treatment. Corticosteroids are a common choice, but if treatment doesn't work, your doctor may prescribe IMBRUVICA® (ibrutinib).^{5,6}

Please see the Important Side Effect Information on pages 6 and 7.
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IMBRUVICA® is an oral, once-daily medication for previously treated cGVHD that works differently from steroids⁷

Unlike steroids, which suppress various elements of immune systems, IMBRUVICA® works by blocking a protein in the blood called Bruton's tyrosine kinase, or BTK.^{7,8} By blocking BTK, IMBRUVICA® inhibits certain immune cells that play a role in cGVHD.

Because BTK is also found in some normal cells, blocking it may cause side effects.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

- **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.
- **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.

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

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.
- 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.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

- **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.
- **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
- rash
- nausea
- fever
- muscle and bone pain
- bruising
- tiredness

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

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

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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Marketed by: Janssen Biotech, Inc. Horsham, PA USA 19044. For more information call 1-877-877-3536.

References: **1.** BMTinfonet.org. Graft vs Host Disease. <https://www.bmtinfonet.org/transplant-article/graft-versus-host-disease-gvhd>. Accessed January 28, 2019. **2.** Filipovich AH, Weisdorf D, Pavletic S, et al. National Institutes of Health consensus development project on criteria for clinical trials in chronic graft-versus-host disease: I. Diagnosis and staging working group report. *Biol Blood Marrow Transplant.* 2005;11(12):945-956. **3.** Im A, Mitchell SA, Steinberg SM, et al. Prevalence and determinants of fatigue in patients with moderate to severe chronic GVHD. *Bone Marrow Transplant.* 2016;51(5):705-712. **4.** Flowers MED, Martin PJ. How we treat chronic graft-versus-host disease. *Blood.* 2015;125(4):606-615. **5.** NCI dictionary of cancer terms. <https://www.cancer.gov/publications/dictionaries/cancer-terms>. Accessed January 28, 2019. **6.** Dubovsky JA, Flynn R, Du J, et al. Ibrutinib treatment ameliorates murine chronic graft-versus-host disease. *J Clin Invest.* 2014;124(11):4867-4876. **7.** IMBRUVICA® (ibrutinib) Prescribing Information. Pharmacyclics LLC. 2019. **8.** Choi SW, Levine JE, Ferrara JL. Pathogenesis and management of graft versus host disease. *Immunol Allergy Clin North Am.* 2010;30(1):75-101. **9.** American Cancer Society. Getting help for diarrhea. <https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/getting-help-for-diarrhea-english.pdf>. Accessed January 28, 2019. **10.** American Cancer Society. Managing cancer-related fatigue at home. <https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/fatigue/managing-cancer-related-fatigue.html>. Accessed January 28, 2019. **11.** American Cancer Society. Preventing infections in people with cancer. <https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/infections/preventing-infections-in-people-with-cancer.html>. Accessed January 28, 2019. **12.** Medline Plus. Taking medicine at home-create a routine. <https://medlineplus.gov/ency/patientinstructions/000613.htm>. Accessed January 28, 2019. **13.** Rolnick SJ, Asche S, Pawloski PA, Bruzek RJ, Hedblom B. Barriers to and facilitators of medication adherence. *Am J Pharm Benefits.* 2013;5(5):209-215.

IMBRUVICA® (ibrutinib) is the first FDA-approved therapy for adult patients who have already been treated with other cGVHD therapies

Now, patients who aren't getting results with corticosteroid therapy have another option.⁷

- In a trial of 42 previously treated patients, 2 out of 3 patients (28 of 42 patients enrolled in the study) had a response (showed improvement) with IMBRUVICA®⁷
- Almost half of patients (20 of 42) in the trial had a response to IMBRUVICA® that lasted for at least 20 weeks⁷

Most Common 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), high blood pressure (hypertension), second primary cancers, and tumor lysis syndrome. The most common side effects in adults with cGVHD are⁷:

- Tiredness
- Bruising
- Diarrhea
- Low platelet count
- Mouth sores (stomatitis)
- Muscle spasms
- Nausea
- Bleeding (hemorrhage)
- Low red blood cell count
- Pneumonia

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

These are not all 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.

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

Tips to help with side effects⁶

To help with diarrhea⁹

Diarrhea can be an uncomfortable side effect for patients taking IMBRUVICA® (ibrutinib). It can also be a sign your cGVHD is getting worse, so be sure to contact your doctor right away if you develop diarrhea or your diarrhea worsens. In the meantime, there are also some tips that can help^{7,8}:

- Stay hydrated. Drink fluids such as water, decaffeinated tea, and clear broth.⁹
- Eat small meals often, and avoid very hot or spicy foods.⁹
- Avoid greasy foods, bran, raw fruits and vegetables, and caffeine.⁹
- Avoid alcohol and drinks with caffeine.⁹
- Do not change your dose unless your doctor advises it.⁷

To help reduce tiredness¹⁰

- Balance periods of light movement with periods of rest.
- Get plenty of sleep, which may include short naps.
- Remain well hydrated throughout the day.
- Eat a well-balanced diet that includes protein.

To help prevent infection¹¹


- Wash hands often and bathe every day.
- Avoid crowds and individuals with contagious diseases.
- Do not keep live plants or fresh flowers in your bedroom.
- Do not clean up droppings from your pets; have someone do this for you.



Once-a-day dosing⁷


You can take IMBRUVICA[®] anywhere. Because IMBRUVICA[®] is an oral medication, you have the freedom to take it at home or wherever you may be. For cGVHD, IMBRUVICA[®] is dosed once a day as either a single 420-mg tablet or three 140-mg capsules. Talk to your doctor about which dosing option is right for you.

IMBRUVICA[®] tablets
come in a blister pack



OR

IMBRUVICA[®] capsules
come in a bottle



- **Take one 420-mg IMBRUVICA[®] tablet by mouth**, at about the same time each day with a glass of water

- **Take three IMBRUVICA[®] 140-mg capsules by mouth**, at about the same time each day with a glass of water

- Do not open, break, cut, crush, or chew IMBRUVICA[®] tablets or capsules
- 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
- 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).

Do not stop taking IMBRUVICA[®] without talking to your doctor. Always take IMBRUVICA[®] exactly as your doctor prescribes.

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

While taking IMBRUVICA[®] (ibrutinib)

- Do not drink grapefruit juice.⁷
- Do not eat grapefruit.⁷
- Do not eat Seville oranges, often used in making marmalade.⁷

These foods may increase the amount of IMBRUVICA[®] in your blood.⁷
For more information about drug interactions, please see the Important Product Information.

Tell your doctor 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 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^{12,13}

- 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 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

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 can 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

Saturday, 8 AM - 5 PM ET

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Resources and support

Here are some organizations that can help you and your caregiver learn more about cGVHD and connect with others in the community:

- Meredith A. Cowden Foundation
 - Cowdenfoundation.org
- Blood & Marrow Transplant Information Network
 - Bmtinfonet.org
- National Bone Marrow Transplant Link
 - Nbmtlink.org
- Leukemia & Lymphoma Society
 - LLS.org
- Lymphoma Research Foundation
 - lymphoma.org
- CancerCare®
 - cancercare.com

Use this space to write down any questions you have for your healthcare professional or notes that you want to remember from your conversation.



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To learn more,
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or call the YOU&i™ Support Program
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