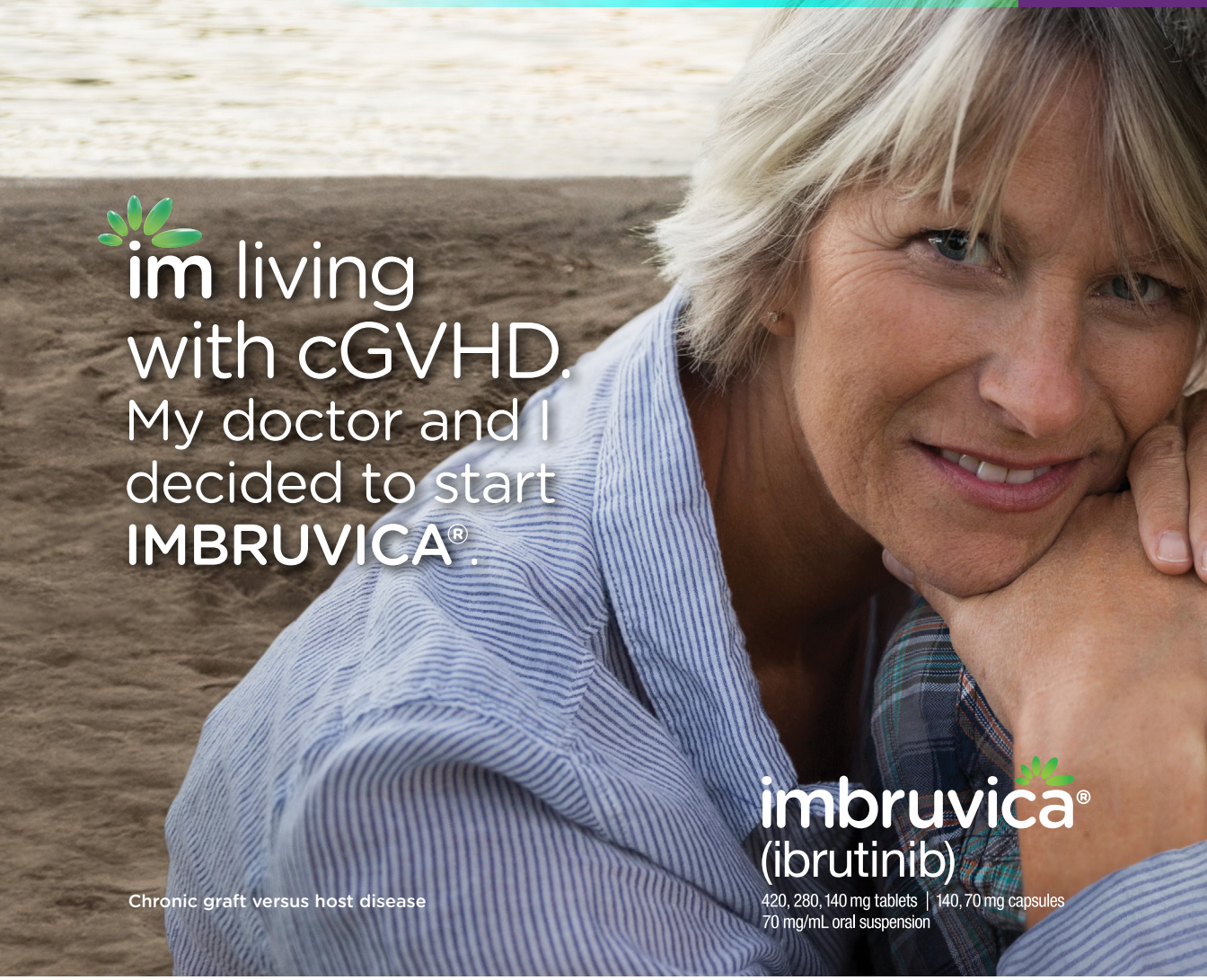

What is IMBRUVICA® (ibrutinib)?

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

- Adults and children 1 year of age and older 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 under 1 year of age.

IMPORTANT SIDE EFFECT INFORMATION

IMBRUVICA® may cause serious side effects, including: bleeding problems (hemorrhage); infections; heart rhythm problems (ventricular arrhythmias, atrial fibrillation, and atrial flutter); heart failure and death; high blood pressure (hypertension); decrease in blood cell counts; second primary cancers; and tumor lysis syndrome (TLS).

Please review the Important Side Effect Information on pages 10 and 11.

Please see the accompanying Important Product Information or go to www.imbruvica.com/prescribing-information.

Welcome to an option for treating cGVHD

Starting treatment with IMBRUVICA® is an important time in your journey with chronic graft versus host disease (cGVHD). This brochure will help you learn more about your condition and how IMBRUVICA® may be able to help.

Researchers continue to learn more about cGVHD. These discoveries have helped them develop oral medicines (medicines taken by mouth) such as IMBRUVICA®.[1,2]

IMBRUVICA® works differently than other treatments such as steroids. For more information on how IMBRUVICA® works, turn to page 6 of this brochure.[1]

IMBRUVICA® is a once-daily, oral treatment option available to treat cGVHD[1]

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

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It is not known if IMBRUVICA® is safe and effective in children under 1 year of age.

IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

IMBRUVICA® may cause serious side effects, including:

- Bleeding problems (hemorrhage)
- Infections
- Heart rhythm problems (ventricular arrhythmias, atrial fibrillation, and atrial flutter); heart failure and death
- High blood pressure (hypertension)
- Decrease in blood cell counts
- Second primary cancers
- Tumor lysis syndrome (TLS)

imbruvica® (ibrutinib)
420, 280, 140 mg tablets | 140, 70 mg capsules
70 mg/mL oral suspension

Please review the Important Side Effect Information on pages 10 and 11.
Please see the accompanying Important Product Information or go to www.imbruvica.com/prescribing-information.

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.

Table of contents

Understanding chronic graft versus host disease (cGVHD)

When you have been diagnosed with cGVHD, it's normal to feel overwhelmed. 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?[3]

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."**

There are two kinds of GVHD that may develop[4]:

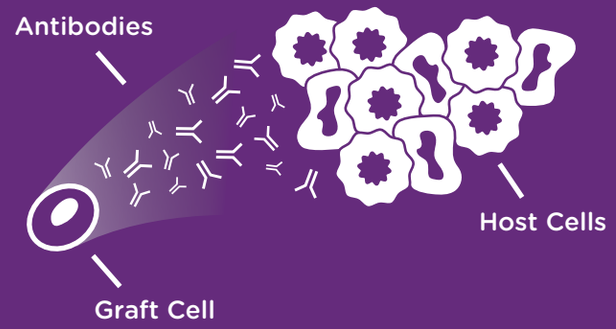
- Acute *(typically happens earlier after transplant)*
- Chronic *(typically occurs later after transplant)*

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

Acute GVHD and cGVHD affect one or more organ systems, and they can continue over a long period of time. Unfortunately, GVHD may occur after receiving a donor stem cell or bone marrow transplant.[3,4]

The role your immune system plays[3,4]

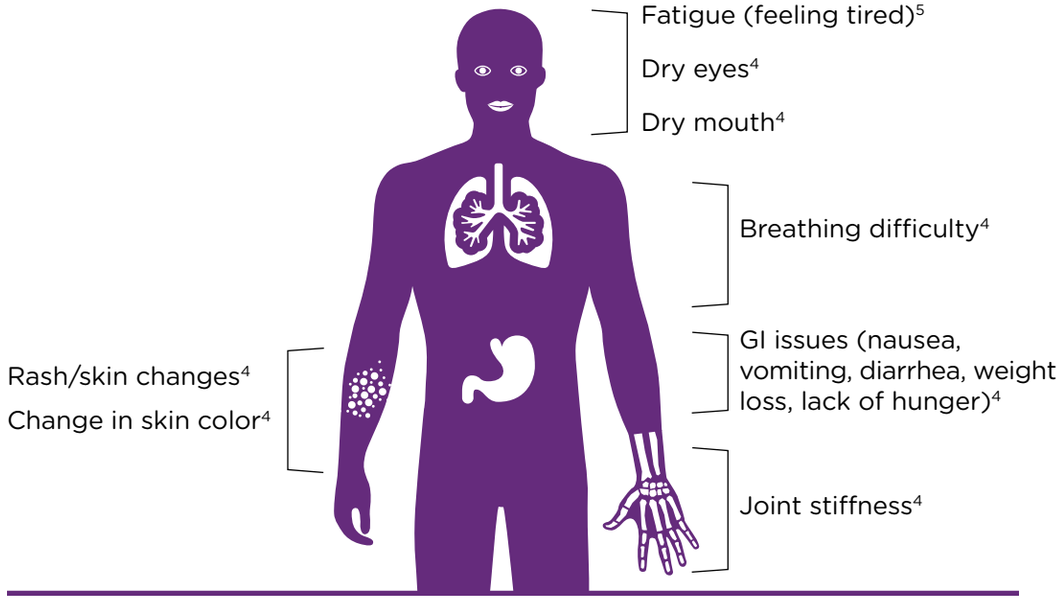
When your **immune system** is working normally, it helps defend your body against harmful invaders, like viruses or bacteria. This helps you stay healthy. GVHD occurs when the graft perceives your own tissues as unfamiliar cells that should be destroyed.



In GVHD, the graft (transplant) cells attack the host (your body) cells using the immune system[4,5]

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. Below are the most common symptoms of cGVHD[4]:



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 things[4]:

- 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 be treated locally with topical therapy.

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).[6]

IMBRUVICA® (ibrutinib) is an oral, once-daily medication for previously treated patients with chronic graft versus host disease (cGVHD) that works differently than steroids[1]

IMBRUVICA® works by blocking a protein in the blood called **B**ruton's **t**yrosine **k**inase, or BTK. 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.

Please see the Important Side Effect Information located on pages 10 and 11.

IMBRUVICA® (ibrutinib) is the first FDA-approved therapy for adult patients who have already been treated with other systemic cGVHD therapies[1]

With IMBRUVICA®, patients who aren't getting results with corticosteroid therapy have another option.

- 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®
- Almost half of patients (20 of 42) in the trial had a response to IMBRUVICA® that lasted for at least 20 weeks

IMBRUVICA® will not work for every patient. Individual results may vary.

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 or severe headache.

imbruvica® (ibrutinib)
420, 280, 140 mg tablets | 140, 70 mg capsules
70 mg/mL oral suspension

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Side effects information

IMBRUVICA® (ibrutinib) may cause serious side effects, including:

- Bleeding problems (hemorrhage)
- Infections
- Heart rhythm problems (ventricular arrhythmias, atrial fibrillation, and atrial flutter); heart failure and death
- High blood pressure (hypertension)
- Decrease in blood cell counts
- 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.

In a clinical trial, **the most common side effects** in adults with chronic graft versus host disease (cGVHD) were:

- Tiredness
- Bruising
- Diarrhea
- Mouth sores (stomatitis)
- Muscle spasms
- Nausea
- Pneumonia

In the cGVHD clinical trial, nearly 1 in 4 of 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.

These are not all possible side effects of IMBRUVICA®. Talk to your healthcare team about how to best manage possible side effects, and if any dose adjustments are needed. You may report side effects to FDA at 1-800-FDA-1088.

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Helpful tips for cGVHD patients taking IMBRUVICA®

Tips to help with diarrhea

Diarrhea can be an uncomfortable side effect for patients taking IMBRUVICA®. 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[1]:

- 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, and caffeine[7]
- Avoid alcohol[7]

To help reduce tiredness[8]

- 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 infection[9]

- 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

Infection is a serious possible side effect of IMBRUVICA®. Notify a healthcare professional immediately if signs of infection (eg, fever, chills, weakness, and confusion) occur.[1]

The info in this brochure is not intended to replace the advice of your doctor. If you have questions about your treatment, be sure to contact your healthcare team.

USES:

What is IMBRUVICA® (ibrutinib)?

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

- Adults and children 1 year of age and older 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 under 1 year of age.

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 at about the same time each day.

IMBRUVICA® comes as capsules, tablets, and oral suspension.

- **If your healthcare provider prescribes IMBRUVICA® capsules or tablets:**
  - 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.
- **If your healthcare provider prescribes IMBRUVICA® oral suspension:**
  - See the detailed Instructions for Use that comes with IMBRUVICA® oral suspension for information about the correct way to give a dose to your child. If you have questions about how to give IMBRUVICA® oral suspension, talk to your healthcare provider.
  - Do not use if the carton seal is broken or missing.
- 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®.
- **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 infection, an increased risk for heart disease, or have had heart rhythm problems in the past. Your heart function will be checked before and during treatment with IMBRUVICA®. 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 tests to check your heart 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.
- **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.
- **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 or children 1 year of age and older with cGVHD include:

- tiredness
- low red blood cell count (anemia)
- bruising
- diarrhea
- low platelet count
- muscle and joint pain
- fever
- muscle spasms
- mouth sores (stomatitis)
- bleeding
- nausea
- stomach pain
- pneumonia
- headache

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 or go to www.imbruvica.com/prescribing-information.

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

Once-a-day dosing[1]

You can take IMBRUVICA® (ibrutinib) anywhere. Because IMBRUVICA® is an oral medication, you have the freedom to take it at home or on the go. For cGVHD, IMBRUVICA® should be taken 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

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

OR

IMBRUVICA® capsules come in a bottle

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

Tablets and capsules are not shown at actual size.

- Do not open, break, or chew capsules, and do not cut, crush, or chew tablets.
- 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.

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While taking IMBRUVICA®[1]

- 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.

Strategies to help you plan your IMBRUVICA® routine[10]

It's important to take your medicines exactly as directed by your doctor. Creating a routine can help you remember. This will help you get the most benefit from your treatment.

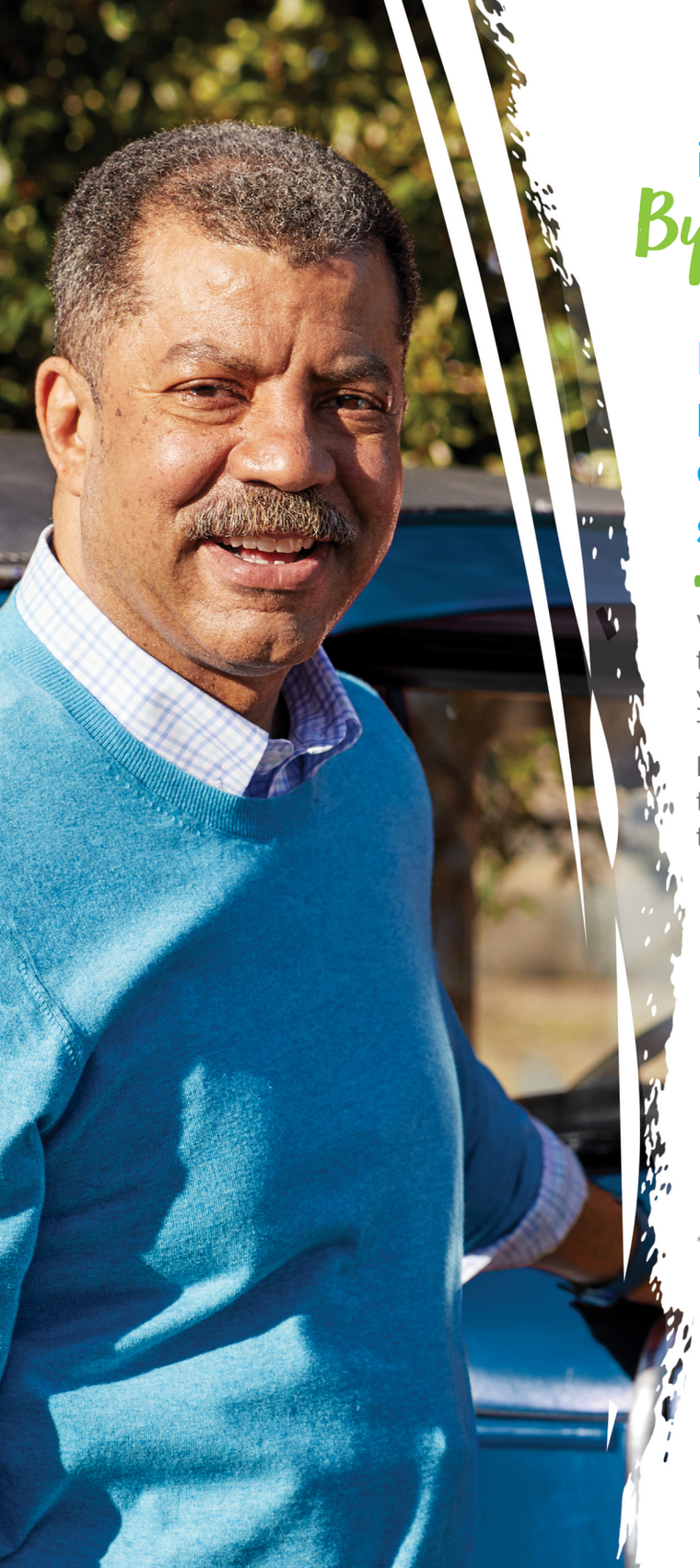
Link it. Take your medicine at the same time as something else you do on a daily basis, like walking the dog or brushing your teeth.[11]

See it. Use reminder notes or put your IMBRUVICA® container in a place you will see it (like next to your bed). Keep IMBRUVICA® out of the reach of children.[11]

Hear it. Set a daily alarm on your phone, watch, or clock to go off when you need to take IMBRUVICA®.[11]

Use your tools. Use tools, such as an app on your smartphone, or a calendar, to set reminders for yourself.[11]

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



imbruvica®
By Your Side
Patient Support

Discover personalized one-on-one support

When starting a new treatment like IMBRUVICA® you may have questions. That's why we created **IMBRUVICA® By Your Side,*** to help you every step of the way.

*IMBRUVICA® By Your Side patient support program is not intended to provide medical advice, replace prescribed treatment plans, or provide treatment or case management services. Patients are advised to always talk to their healthcare provider and treatment team about any medical decisions and concerns they may have.

IMBRUVICA® By Your Side Ambassadors†

- Speak to your own, dedicated ambassador each time you call throughout your treatment journey
- One-on-one support to help you stay on track with your prescribed treatment plan
- Receive help developing routines and understanding treatment costs

Insurance Specialists

- Guide you through the insurance process
- Identify potential savings on the cost of your prescription
- Explain the role of specialty pharmacies

Financial Assistance

- Support for federally funded Medicare, Medicaid, and other government insurance plans
- Patients on commercial insurance may be eligible to pay as little as $0 per prescription‡ with their IMBRUVICA® Copay Card

For more in-depth information, visit **ImbruvicaByYourSide.com** or call **1-888-YourSide (1-888-968-7743) Monday-Friday,** 8 AM - 8 PM ET

†By Your Side Ambassadors are provided by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie Company and do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

‡Eligibility: Available to patients with commercial insurance coverage for IMBRUVICA® (ibrutinib) who meet eligibility criteria. This copay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. For full Terms and Conditions, visit https://www.imbruvica.com/imbruvica-by-your-side or call 1-888-968-7743 for additional information. For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit https://www.pharmacyclics.com/privacy-notice.html#info_pcp.

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Resources and support

Below are some organizations that can help you and your caregiver learn more about chronic graft versus host disease (cGVHD) and connect with others in the community:

Meredith A. Cowden Foundation	www.Cowdenfoundation.org
Blood & Marrow Transplant Information Network	www.BMTinfonet.org
National Bone Marrow Transplant Link	www.NBMTlink.org
Leukemia & Lymphoma Society	www.LLS.org
Lymphoma Research Foundation	www.lymphoma.org
Cancer*Care*®	www.cancercare.org

Use this space, and the space provided on page 19, to write down any questions you may have for your healthcare team or notes that you want to remember from your conversation.

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Get the most out of your visits by asking questions

You may have questions for your healthcare team about your treatment plan.

Remember to add your questions to a journal, smartphone app, or the space provided on the next page.

The following questions can help you start a conversation with your healthcare team:

- How will I know if my treatment is working?
- What kinds of side effects should I expect with my treatment?
- What should I do if I have side effects?
- Is my experience what you usually see in other patients with chronic graft versus host disease (cGVHD)?
- How will I know if my cGVHD is getting worse?

References: 1. IMBRUVICA® (ibrutinib) Prescribing Information. **2.** Socié G, Ritz J. Current issues in chronic graft-versus-host disease. *Blood.* 2014;124(3):374-384. **3.** BMTinfonet.org. Graft-versus-Host-Disease (GHD). https://www.bmtinfonet.org/transplant-article/graft-versus-host-disease-gvhd. Accessed January 6, 2021. **4.** 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):945-955. **5.** 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. **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.** 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. Updated April 2020. Accessed January 6, 2021. **8.** 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. Updated April 10, 2020. Accessed January 6, 2021. **9.** 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 6, 2021. **10.** Borgsteede SD, Westerman MJ, Kok IL, Meeuse JC, de Vries TPGM, Hugtenburg JG. Factors related to high and low levels of drug adherence according to patients with type 2 diabetes. *Int J Clin Pharm.* 2011;33(5):779-787. **11.** Medline Plus. Taking medicine at home-create a routine. https://medlineplus.gov/ency/patientinstructions/000613.htm. Accessed January 6, 2021.

Notes

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

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IMPORTANT SIDE EFFECT INFORMATION (CONT'D)

IMBRUVICA® may cause serious side effects, including: bleeding problems (hemorrhage); infections; heart rhythm problems (ventricular arrhythmias, atrial fibrillation, and atrial flutter); heart failure and death; high blood pressure (hypertension); decrease in blood cell counts; second primary cancers; and tumor lysis syndrome (TLS).

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