

# Treating childhood cGVHD with IMBRUVICA®

For ages 1 year  
and older after  
failure of one  
or more lines of  
systemic therapy

cGVHD=Chronic graft versus host disease

imbruvica®  
(ibrutinib)

420, 280, 140 mg tablets | 140, 70 mg capsules  
70 mg/mL oral suspension

## 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.

## SELECT 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).

**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.

**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](http://www.imbruvica.com/prescribing-information).**

## The first and only FDA-approved treatment in a liquid form for children 1 year to less than 12 years with previously treated cGVHD

If your child's medication for cGVHD isn't working, you have an option. Unlike other cGVHD treatments such as steroids, IMBRUVICA® (ibrutinib) works by blocking a protein in the blood, called Bruton's tyrosine kinase, or BTK. By blocking BTK, IMBRUVICA® inhibits certain immune cells that play a role in cGVHD.

**To help you learn more, the following pages provide an overview of IMBRUVICA®, helpful tips, and how to get personal support during the treatment journey.**

### SELECT 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
- Tumor lysis syndrome (TLS)

The information in this brochure is not intended to replace the advice of a child's doctor. If you have any questions about IMBRUVICA® treatment, be sure to contact the child's healthcare team.

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## Quick facts about cGVHD

When a child has been diagnosed with cGVHD, it's normal to feel overwhelmed. Each cGVHD journey is different, so learning about why a patient's body is reacting the way it is can help you feel more at ease. Focusing on what you can control can better manage a child's cGVHD symptoms.

### What is cGVHD?<sup>2</sup>

**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** (a child's body) as being friendly. In fact, it sees their body as a “**threat.**”

### There are 2 kinds of GVHD that may develop<sup>3</sup>:

- 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.

GVHD may occur after receiving a donor stem cell or bone marrow transplant. Unfortunately, both acute and chronic forms of GVHD may continue over a long period of time.<sup>2,3</sup>

### The role of the immune system<sup>2,3</sup>

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

## Understanding symptoms

With cGVHD, a child's symptoms could last months—or even years—and can affect many different areas of the body. While some symptoms may be mild, others could be moderate or severe. The most common symptoms of cGVHD include<sup>3</sup>:

- Fatigue (feeling tired)<sup>4</sup>
- Dry eyes and/or mouth<sup>3</sup>
- Rash/skin changes<sup>3</sup>
- Change in skin color<sup>3</sup>
- Breathing difficulty<sup>3</sup>
- Joint stiffness<sup>3</sup>
- GI issues (nausea, vomiting, diarrhea, weight loss, lack of hunger)<sup>3</sup>

Every child is different. Parents and caregivers should let the healthcare team know how the child is feeling and if they are experiencing any new symptoms. If a child is feeling mentally or physically tired, for example, it's important to let the healthcare team know.

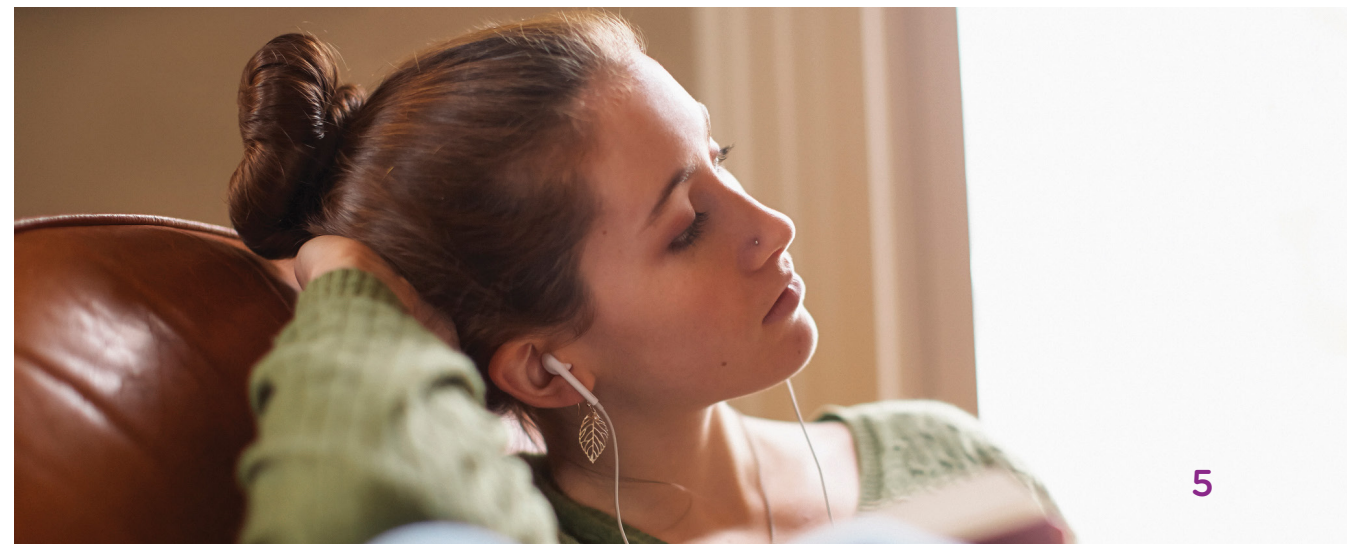
## How is cGVHD treated?

When considering your cGVHD treatment, the child's doctor will look at how severe their symptoms are. The **severity** of cGVHD depends on 2 things<sup>3</sup>:

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

Children 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, the child's doctor may prescribe IMBRUVICA® (ibrutinib).<sup>5</sup>



## What is IMBRUVICA® (ibrutinib)?

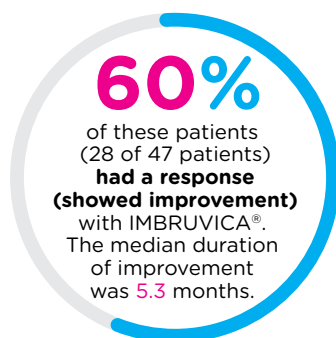
IMBRUVICA® is an oral, once-daily medication for previously treated patients with chronic graft versus host disease (cGVHD) that works differently than steroids.<sup>1</sup> IMBRUVICA® works by blocking a protein in the blood called **B**ruton's **t**yrosine **k**inase, or BTK. By blocking BTK, IMBRUVICA® 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.

## Shown to be effective in a clinical trial

IMBRUVICA® is the first and only FDA-approved treatment for patients 1 year and older who have already been treated with other systemic cGVHD therapies.<sup>1</sup> IMBRUVICA® was studied in a 25-week (and beyond) clinical trial of 47 previously treated patients with moderate to severe cGVHD, ranging in age from 1 to 22 years of age:



Individual results may vary.

### SELECT IMPORTANT SIDE EFFECT INFORMATION

**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.

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## Possible side effects of IMBRUVICA® (ibrutinib)

**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).\*

\*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 of IMBRUVICA® in the clinical trial of children and young adults ages 1 - <22 years with cGVHD included:

- Decrease in red blood cells
- Muscle and bone pain
- Fever
- Diarrhea
- Pneumonia
- Abdominal pain
- Mouth sores (stomatitis)
- Decrease in platelet cells
- Headache

In the cGVHD clinical trial, 23% of young patients (12 months to 21 years old) stopped taking IMBRUVICA® because of side effects.

These are not all the possible side effects of IMBRUVICA®. Others may occur. Call the child's doctor for medical advice about side effects. Side effects can be reported to FDA at 1-800-FDA-1088.



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## Helpful tips for cGVHD patients taking IMBRUVICA®



### Tips to help with diarrhea<sup>6</sup>

Diarrhea can be an uncomfortable side effect for patients taking IMBRUVICA®. Be sure to contact the child's healthcare team right away if they develop diarrhea or their diarrhea worsens. Tips to help with diarrhea include:

- Drinking clear fluids such as water or broth
- Eating small meals often, and avoiding spicy food
- Avoiding greasy food, raw fruits and vegetables, and caffeine



### To help reduce tiredness, ensure that children<sup>7</sup>:

- 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 reduce the risk of infection<sup>8</sup>

- Make sure children wash their hands often and bathe every day
- Keep children away from crowds or people with contagious diseases
- Don't keep live plants or flowers in a child's bedroom
- Do not let children come into contact with pet droppings

**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.<sup>1</sup>**

The information in this brochure is not intended to replace the advice of a child's doctor. If you have any questions about IMBRUVICA® treatment, be sure to contact the child's 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® (ibrutinib)?

**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                         | • muscle spasms            |
| • low red blood cell count (anemia) | • mouth sores (stomatitis) |
| • bruising                          | • bleeding                 |
| • diarrhea                          | • nausea                   |
| • low platelet count                | • stomach pain             |
| • muscle and joint pain             | • pneumonia                |
| • fever                             | • 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](http://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.



## Giving your child IMBRUVICA® (ibrutinib)

This guide provides an overview for giving liquid IMBRUVICA® oral suspension to IMBRUVICA® patients. This information does not take the place of talking to your healthcare provider about a patient's medical condition or treatment.

**This guide is not intended to replace the INSTRUCTIONS FOR USE provided with IMBRUVICA® oral suspension. For information about the correct way to give a dose to your child, read the INSTRUCTIONS FOR USE before giving IMBRUVICA® to children, and every time you get a refill. There may be new information.**

Call your healthcare provider or 1-877-877-3536 if you need help or have any questions about how to give IMBRUVICA® the right way.



**Important information you need to know before giving IMBRUVICA® to children.**

### IMBRUVICA® is for oral use only.

- Give IMBRUVICA® exactly as your healthcare provider tells you to.
- If you miss giving a dose it can be given as soon as possible on the same day. Do not give more than the prescribed dose in 1 day.
- ⚠ If the child takes too much IMBRUVICA®, call your healthcare provider for help.
- Keep these instructions for future use.

### 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.

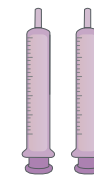
### IMBRUVICA® comes as capsules, tablets, and oral suspension.

- **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 a 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.

## IMBRUVICA® carton contents



1 bottle of IMBRUVICA® with pre-inserted bottle adapter



2 reusable 3-mL oral dosing syringes measuring in 0.1-mL increments

**Do not remove the bottle adapter.**

⚠ **Only use the syringes that come with IMBRUVICA®.**

**Do not** use the syringes for other patients or with other medicines.

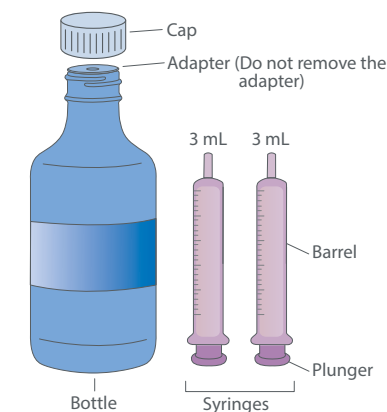
⚠ If you cannot read the markings on the syringes, throw them away and call 1-877-877-3536 to get new ones.

## Prepare supplies



### Gather and check supplies

- Check the child's prescribed dose in milliliters (mLs). Find this mL marking on the syringe.
- If the dose is more than the marking on the syringe, split the dose between syringes as prescribed.
- Gather bottle and syringe(s).
- Check the bottle and make sure that the bottle has **IMBRUVICA® Oral Suspension** printed on it and the expiration date ("EXP") has not passed.



⚠ **Do not** use IMBRUVICA® after the expiration date printed on the carton and the bottle after "EXP."

⚠ **Do not** use if the IMBRUVICA® carton seal appears to be tampered with.

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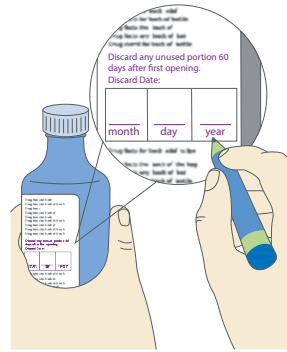
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## Prepare supplies (cont'd)

### 2 Record or check discard date

- Record the date that is 60 days from the day the bottle is opened underneath the words "Discard Date."
- Use IMBRUVICA® (ibrutinib) within 60 days after opening.

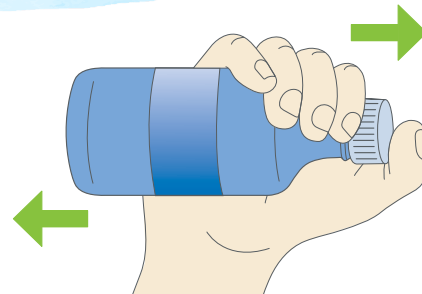
⚠ **Do not** use IMBRUVICA® past the discard date recorded on the bottle.



## Prepare the dose by filling the syringe

### 3 Shake bottle

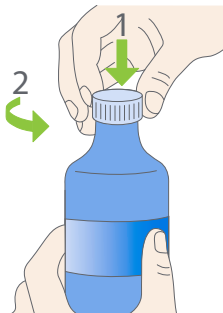
- Shake well before each use.



### 4 Remove cap from bottle

- Press down and twist the cap counterclockwise to remove it from the bottle.
- If there is fluid on top of the adapter, you may wipe it with clean disposable tissue.

**Do not remove the bottle adapter.**



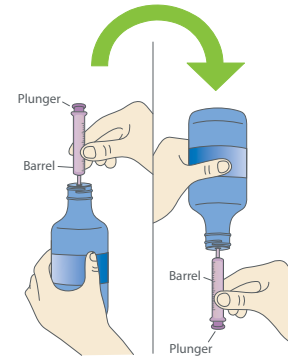
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### Attach syringe to bottle

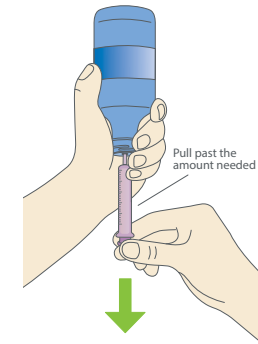
- Make sure the syringe is clean and dry before use.
- Push the plunger down all the way.
- Gently insert tip of the syringe into the adapter.
- Turn the assembled bottle and syringe upside down.



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### Fill syringe

- Slowly pull the syringe plunger down, past the number of mLs for your prescribed dose.
- Check for air bubbles and proceed to Step 7 for instructions on how to remove air bubbles.



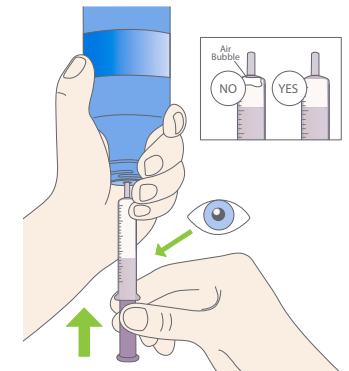
7

### Remove air bubbles and adjust to the prescribed dose

- Hold the syringe and tap the sides to send bubbles to the tip.
- With the syringe attached to the bottle, push the plunger up to remove the air bubbles from the top.
- After the bubbles are removed, push the plunger up until the top of the colored plunger is even with the markings on the syringe for the dose.

⚠ Air bubbles must be removed to ensure the correct dose.

**Note:** Repeat steps 6 and 7 if any air bubbles remain.



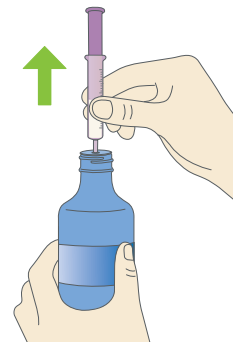
8

### Remove syringe from bottle

- Turn the assembled bottle upright.
- Hold the middle of the syringe and carefully remove it from the bottle.
- Place the bottle aside.

⚠ **Do not** touch the plunger of the syringe to avoid accidentally spilling the medicine before you are ready.

**Note:** If more than 1 syringe is needed to give the full dose, repeat steps 5 to 8 with the second syringe to complete the prescribed dose.





## Give the dose to the child

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### Give IMBRUVICA® (ibrutinib)

- Place the tip of the syringe along the inside of the child's cheek.
- Slowly push the plunger all the way in to give the entire dose.
- Repeat with second syringe if needed to complete the prescribed dose.



**Note:** IMBRUVICA® must be given as soon as possible after being drawn from the bottle.

**Note:** Make sure the child drinks water after swallowing the dose of medicine.

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### Recap bottle

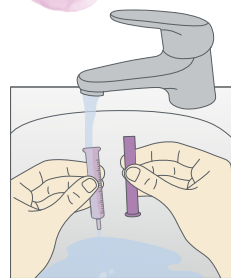
- Place the cap back on the IMBRUVICA® bottle.
- Make sure the bottle is tightly closed between each use.



11

### Rinse syringe

- Remove plunger from the syringe, rinse only with water, and air dry.
  - Store the syringe in a clean, dry place.
- ⚠ Do not** clean the syringe with soap or put in the dishwasher.



### How to store IMBRUVICA® Oral Suspension

- Store the bottle between 36°F and 77°F (2°C and 25°C).
- ⚠ Do not** freeze.
- **Store IMBRUVICA® and all medications out of sight and reach of children.**

### How to dispose of IMBRUVICA®

- ⚠** Dispose of (throw away) any unused medicine within 60 days after first opening of the bottle. At the same time throw away any used or unused syringes.
- Ask your pharmacist how to properly dispose of the medicine.
  - For syringe disposal, rinse and place in household trash.

## During IMBRUVICA® treatment, make sure the children<sup>1</sup>:

- 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 their blood.

## Ways to help plan a child's IMBRUVICA® routine

It's important that children take their medicine exactly as directed by their doctor. IMBRUVICA® should be taken about the same time each day. Creating a routine can help you remember, and help children get the most benefit from their treatment.



**Link it.** Give children IMBRUVICA® at the same time as something else the family does on a daily basis, like walking the dog or preparing for bed.



**Hear it.** Set a daily alarm on your phone, watch, or clock to go off when it's time to give IMBRUVICA®.



**See it.** Use reminder notes or put the IMBRUVICA® medicine in a place you will see it (like on the kitchen counter). Keep IMBRUVICA® out of the reach of children.



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

**Do not stop giving IMBRUVICA® to a child without talking to their doctor. Always give IMBRUVICA® exactly as their doctor prescribes.**

**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](http://www.imbruvica.com/prescribing-information).



## Discover personalized one-on-one support

When children are starting a treatment like IMBRUVICA® (ibrutinib) for the first time, parents and caregivers may have questions. **IMBRUVICA® By Your Side** is here to help enrolled patients by providing one-on-one support and treatment-related resources.

\*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 and caregivers 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 you can call throughout the treatment journey
- One-on-one support to help children stay on track with their prescribed treatment plan
- Receive help developing routines and understanding treatment costs

### **Insurance specialists**

- Help you understand your insurance coverage and navigate any changes
- Estimate your out-of-pocket expenses
- Identify potential financial support options

### **Financial assistance**

- Support for pediatric patients who are on federally funded insurance plans or are uninsured
- If the child is eligible and is covered by commercial insurance, you may pay as little as \$0 per prescription† for IMBRUVICA® with the IMBRUVICA® Copay Card

Enroll in **IMBRUVICA® By Your Side** to connect with an ambassador today. Visit [ImbruvicaByYourSide.com](https://www.imbruvica.com/by-your-side) 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 and caregivers to their healthcare provider 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](https://www.pharmacyclics.com/privacy-notice.html#info_pcp).

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## Helpful resources

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

**Meredith A. Cowden Foundation**      [www.Cowdenfoundation.org](http://www.Cowdenfoundation.org)

**Blood & Marrow Transplant Information Network**      [www.BMTinfonet.org](http://www.BMTinfonet.org)

**National Bone Marrow Transplant Link**      [www.NBMTlink.org](http://www.NBMTlink.org)

**Leukemia & Lymphoma Society**      [www.LLS.org](http://www.LLS.org)

**Lymphoma Research Foundation**      [www.lymphoma.org](http://www.lymphoma.org)

**CancerCare®**      [www.cancercares.org](http://www.cancercares.org)

Use these pages to write down any questions you may have for the healthcare team or notes that you want to remember from your conversation.

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## Notes

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## Get the most out of your visits by asking questions

You may have questions for your healthcare team about a child's treatment plan.

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

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

- How will I know if the child's treatment is working?
- What kinds of side effects should I watch for with the child's treatment?
- What should I do if the child has side effects?
- Is the child's experience what you usually see in other young patients with chronic graft versus host disease (cGVHD)?
- How will I know if the child's cGVHD is getting worse?

**References:** 1. IMBRUVICA® (ibrutinib) Prescribing Information. 2. BMTinfonet.org. Graft-versus-Host-Disease (GVHD). <https://www.bmtinfonet.org/transplant-article/graft-versus-host-disease-gvhd>. Accessed August 5, 2022. 3. 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. 4. 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. 5. 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. 6. American Cancer Society. Getting help for diarrhea. <https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/getting-help-for-diarrhea.pdf>. Updated April 2020. Accessed August 22, 2022. 7. 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 August 5, 2022. 8. 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 August 5, 2022.

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When systemic therapies  
haven't worked

**IMBRUVICA<sup>®</sup>** is  
the first and only  
FDA-approved  
cGVHD treatment  
for patients  
1 year and older



To learn more,  
visit [www.IMBRUVICA.com/cGVHD](http://www.IMBRUVICA.com/cGVHD)  
or call **1-877-877-3536**

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### **SELECT IMPORTANT SIDE EFFECT INFORMATION**

**IMBRUVICA<sup>®</sup> 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).

**The most common side effects of IMBRUVICA<sup>®</sup> 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.

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