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

PREPARING AND DOSING GUIDE

IMBRUVICA® (ibrutinib)
Oral Suspension, for oral use

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

This Preparing and Dosing Guide is not intended to replace the **INSTRUCTIONS FOR USE** provided with IMBRUVICA® oral suspension. Read the **INSTRUCTIONS FOR USE** before you give IMBRUVICA® to your child, and each time you get a refill. There may be new information.

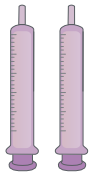
Call your healthcare provider or 1-877-877-3536 if you need help or have any questions about how to give IMBRUVICA® the right way.

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.

IMBRUVICA® carton contents

1 bottle of IMBRUVICA® with pre-inserted bottle adapter; **do not remove bottle adapter**



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

⚠ **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.

Please review the Important Side Effect Information on pages 6-8. Please see the full Important Product Information at imbruvica.com/prescribing-information

Prepare supplies

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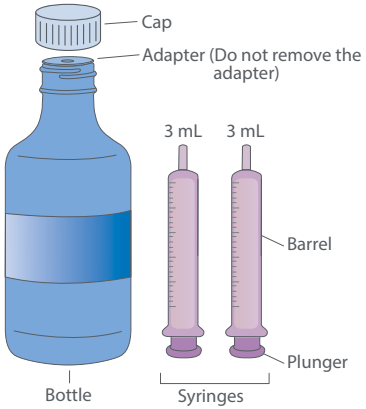
1 Gather and check supplies

- 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."

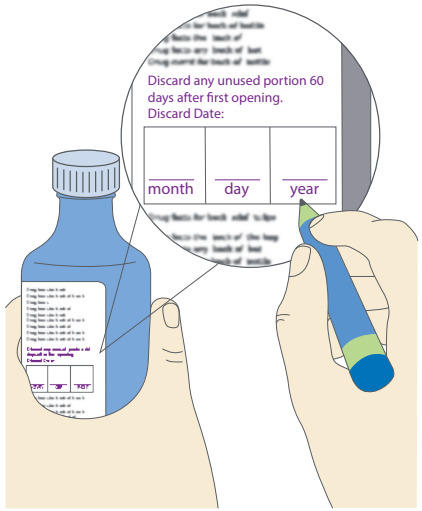
⚠ **Do not** use if the IMBRUVICA® carton seal appears to be tampered with.



2 Record or check the discard date

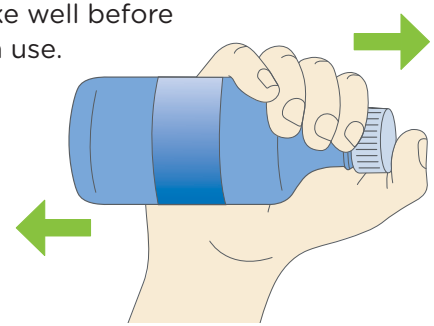
- Record the date that is 60 days from the day the bottle is first opened underneath the words "Discard Date."
- Use IMBRUVICA® within 60 days after opening.

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



3 Shake bottle

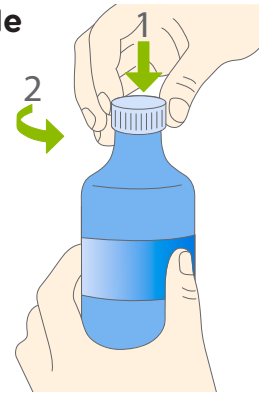
- Shake well before each use.



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 a clean disposable tissue.

Do not remove the bottle adapter.



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Prepare the dose by filling the syringe

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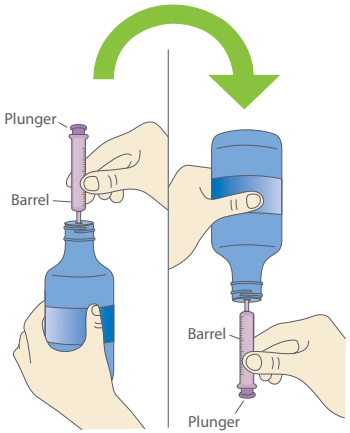
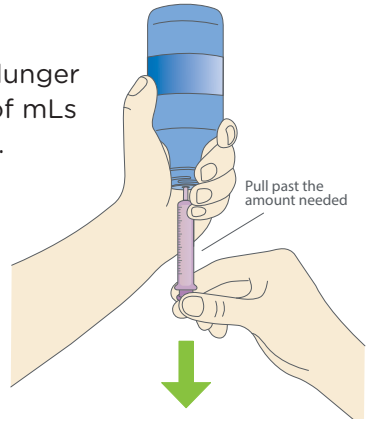
5 Attach syringe to bottle

- 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.



6 Fill syringe

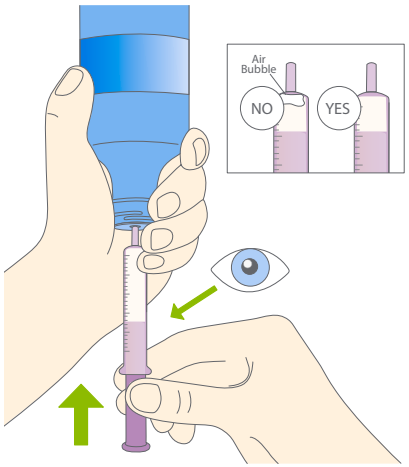
- Slowly pull the syringe plunger down, past the number of mLs for your prescribed dose.
- Check for air bubbles and proceed to Step 7 for instructions on how to remove air bubbles.



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.

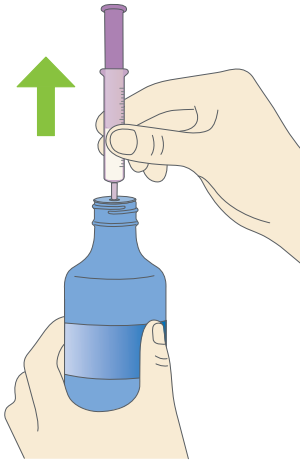


Note: Repeat steps 6 and 7 if any air bubbles remain.

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.

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Give the dose to the child

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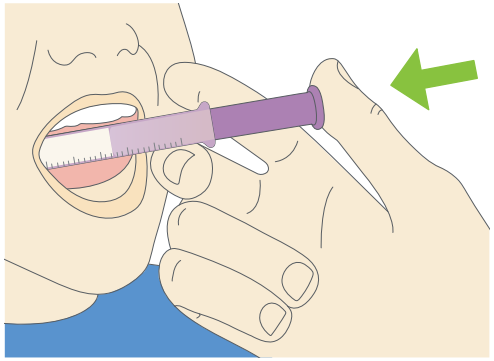
9 Give IMBRUVICA® (ibrutinib)

- 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.



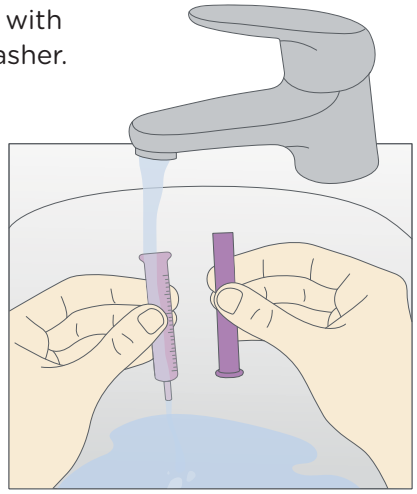
10 Recap bottle

- 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.



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Storage and disposal

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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®

- ⚠ Throw away (dispose of) 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.

Please review the Important Side Effect Information on pages 6-8. Please see the full Important Product Information at imbruvica.com/prescribing-information

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 or are taking a blood thinner medicine.
- have an infection.
- 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 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 or give IMBRUVICA®?

- Take or give IMBRUVICA® exactly as your healthcare provider tells you to take it.
- Take or give 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 take or give a dose. If you have questions about how to take or give IMBRUVICA® oral suspension, talk to your healthcare provider.
  - — Do not use if the carton seal is broken or missing.

Please review the Important Side Effect Information on pages 7 and 8. Please see the full Important Product Information at imbruvica.com/prescribing-information

IMPORTANT SIDE EFFECT INFORMATION (cont'd)

- If you miss a dose of IMBRUVICA®, take or give it as soon as you remember on the same day. Take or give the next dose of IMBRUVICA® at the regular time on the next day. Do not take or give 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, or small red or purple spots on the skin; 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 feeling 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.
- **Liver problems.** Liver problems, which may be severe or life-threatening, or lead to death, can happen in people treated with IMBRUVICA®. Your healthcare provider will do blood tests to check your liver before and during treatment with IMBRUVICA®. Tell your healthcare provider or get medical help right away if you have any signs of liver problems, including stomach pain or discomfort, dark-colored urine, or yellow skin and eyes.
- **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.

Please review the Important Side Effect Information on pages 6 and 8. Please see the full Important Product Information at imbruvica.com/prescribing-information

IMPORTANT SIDE EFFECT INFORMATION (cont'd)

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, bone, and joint pain; fever; muscle spasms; mouth sores (stomatitis); bleeding; nausea; stomach pain; pneumonia; and 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 healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/PatientAccessSupport to learn more.

USE

What is IMBRUVICA® (ibrutinib)?

IMBRUVICA® 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.

Please review the Important Side Effect Information on pages 6 and 7. Please see the full Important Product Information at imbruvica.com/prescribing-information

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