

INSTRUCTIONS FOR USE

IMBRUVICA (im-BRU-vih-kuh) (ibrutinib) oral suspension

This Instructions for Use contains information about how to prepare and take or give a dose of IMBRUVICA oral suspension.

Read this Instructions for Use before you take or give IMBRUVICA and each time you get a refill. There may be new information.

This Instructions for Use does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment.

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

Important information you need to know before taking or giving IMBRUVICA.

- **IMBRUVICA is for oral use only.**
- Take or give IMBRUVICA exactly as your healthcare provider tells you to.
- If you miss a dose of IMBRUVICA, it can be taken or given as soon as possible on the same day.
Do not take or give more than the prescribed dose in 1 day.
- ⚠ If you or your child take too much IMBRUVICA, call your healthcare provider for help.
- Keep these instructions for future use.


Each IMBRUVICA carton contains (see **Figure A**):

- 1 bottle of IMBRUVICA (called 'bottle' in this Instructions for Use) with pre-inserted bottle adapter (called 'adapter' in this Instructions for Use). **Do not remove the bottle adapter.**
- 2 reusable 3 mL oral dosing syringes (called 'syringe' in this Instructions for Use) 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.

Preparing and taking or giving a dose of IMBRUVICA

Step 1: Gather and check supplies.

- Check the 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) (see **Figure A**).
- 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 “EXP” date printed on the carton and on the bottle.

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

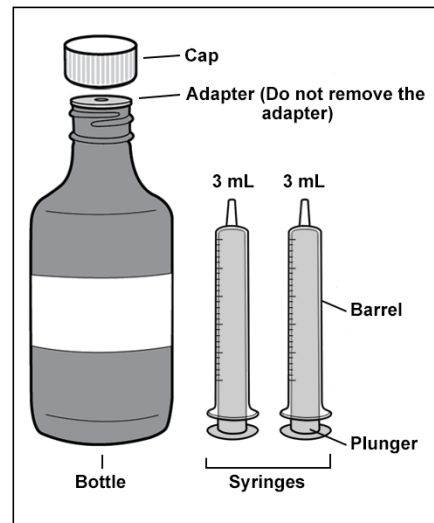


Figure A

Step 2: Record or check the discard date.

- When opening the bottle for the first time, record the date that is 60 days from the day the bottle is opened underneath the words “Discard Date” (see **Figure B**).
- Use IMBRUVICA within 60 days after first opening the bottle.

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

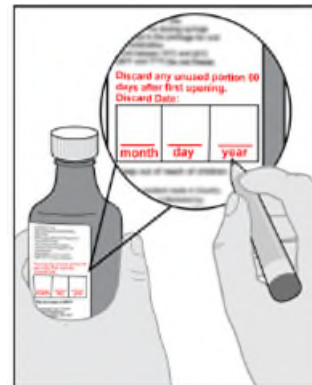


Figure B

Step 3: Shake the bottle.

- Shake the bottle well before each use (see **Figure C**).

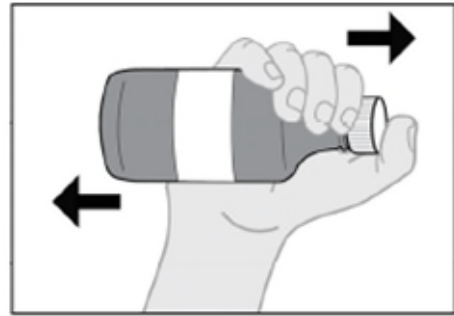


Figure C

Step 4: Remove the cap from the bottle.

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

Do not remove the bottle adapter.

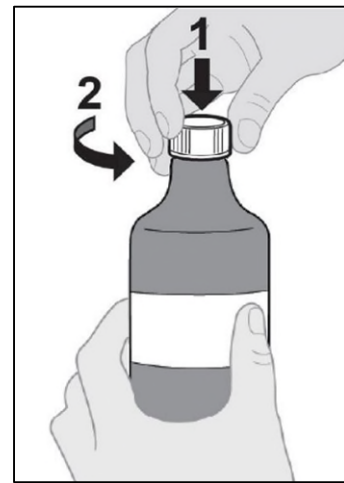


Figure D

Step 5: Attach the syringe to the 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 (see **Figure E**).

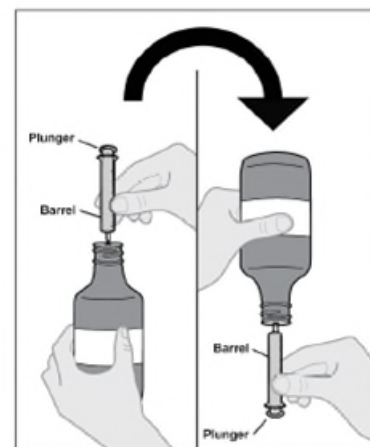


Figure E

Step 6: Fill the syringe.

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

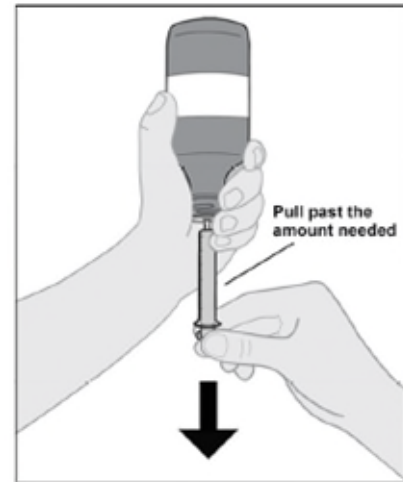



Figure F

Step 7: Remove air bubbles and adjust to the prescribed dose (mL).

- 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 (see **Figure G**).
- 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 prescribed dose.

 Air bubbles must be removed to ensure the correct dose.

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

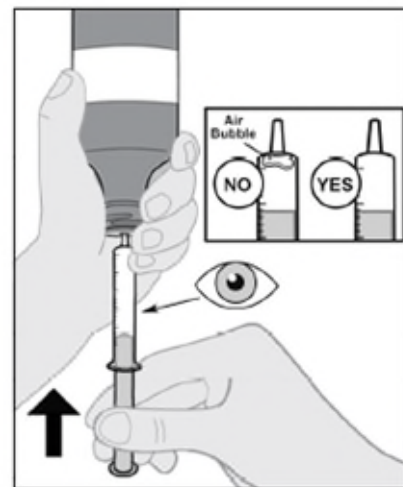


Figure G

Step 8: Remove the syringe from the bottle.

- Turn the assembled bottle upright.
- Hold the middle of the syringe and carefully remove it from the bottle (see **Figure H**).
- Place the bottle aside.

⚠ Do not touch the plunger of the syringe to avoid accidentally spilling the medicine before you are ready to take or give the dose.

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

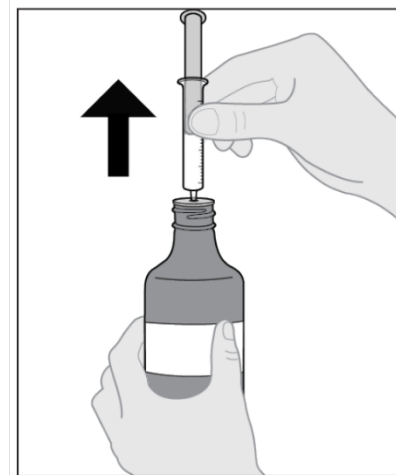


Figure H

Step 9: Take or give IMBRUVICA.

- Place the tip of the syringe along the inside of the cheek.
- Slowly push the plunger all the way in to take or give the entire dose (see **Figure I**).
- Repeat with second syringe if needed to complete the prescribed dose.

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

Note: After swallowing the dose of medicine make sure to drink water.

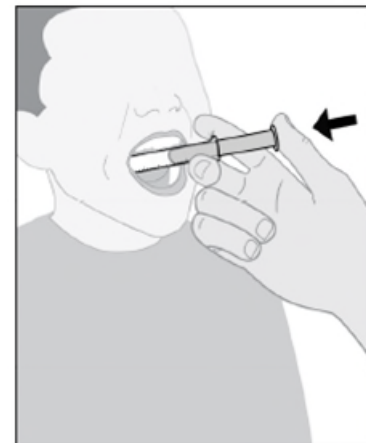


Figure I

Step 10: Recap the bottle.

- Place the cap back on the IMBRUVICA bottle (see **Figure J**).
- Make sure the bottle is tightly closed between each use.



Figure J

Step 11: Rinse the syringe.

- Remove the plunger from the syringe.
- Rinse the plunger and the syringe only with water and air dry (see **Figure K**).
- Store the syringe in a clean, dry place.

⚠ Do not clean the syringe with soap or in the dishwasher.

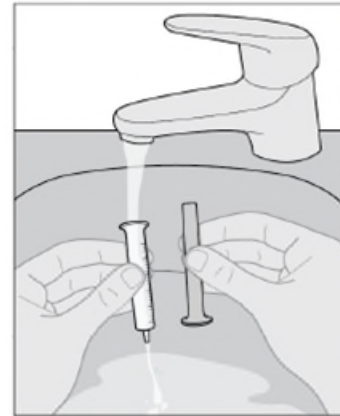


Figure K

Turn over for more information →

How to store IMBRUVICA Oral Suspension

- Store the bottle between 36°F and 77°F (2°C and 25°C).
- **⚠ Do not** freeze.
- IMBRUVICA oral suspension comes in a bottle with a child-resistant cap.
- **Store IMBRUVICA and all medications out of the 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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Distributed and Marketed by:
Pharmacyclics LLC
South San Francisco, CA 94080 USA
and
Marketed by:
Janssen Biotech, Inc.
Horsham, PA 19044 USA

Patent <http://www.imbruvica.com>
IMBRUVICA® is a registered trademark owned by Pharmacyclics LLC

© 2024 Pharmacyclics LLC
© 2024 Janssen Biotech, Inc.
20080493
Revised: 2/2024