

INSTRUCTIONS FOR USE
XROMI® (ex-ro-mee)
(hydroxyurea)
oral solution

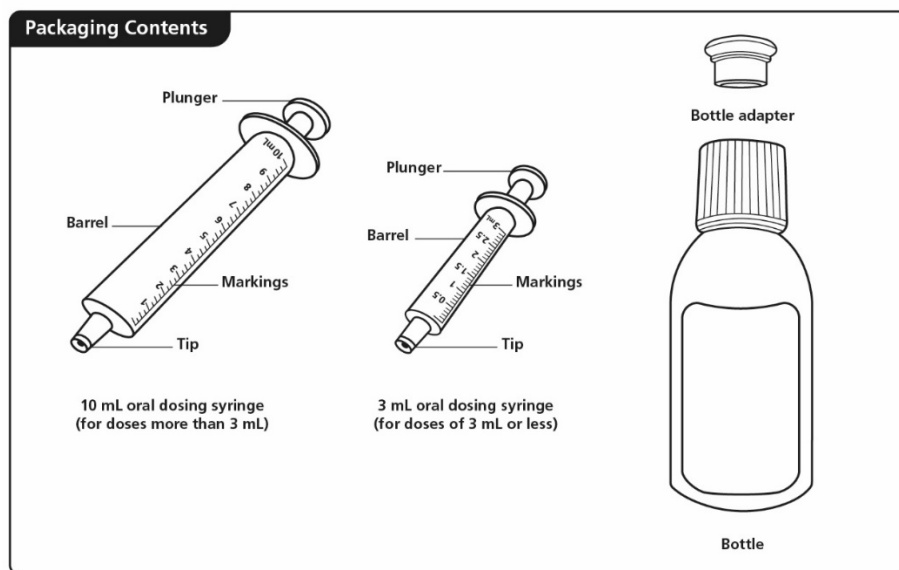
Read these Instructions for Use before your child starts taking XROMI, and each time you get a refill. There may be new information. This Instructions for Use does not take the place of talking to your child's healthcare provider about your child's medical condition or treatment.

Important information:

- **Always use the oral dosing syringe provided with your child's XROMI oral solution to measure your child's prescribed dose.** Ask your child's healthcare provider or pharmacist to show you which oral dosing syringe to use and how to measure your child's prescribed dose if you are not sure.
- Wash your hands with soap and water before and after handling XROMI oral solution and oral dosing syringes.
- Wear disposable gloves when handling XROMI oral solution and oral dosing syringes.
- Avoid contact with the oral solution. If contact with the oral solution happens on the skin, nose, or mouth, wash the area right away and thoroughly with soap and water. If contact with the oral solution happens in the eyes, flush the eyes thoroughly with water and isotonic eyewash used for that purpose for at least 15 minutes.
- If the oral solution is spilled, wipe it up right away with a damp disposable towel. Throw the damp disposable towel away in a closed container such as a plastic bag. The spill area should then be cleaned up using a detergent solution followed by clean water.
- Do not shake the bottle.

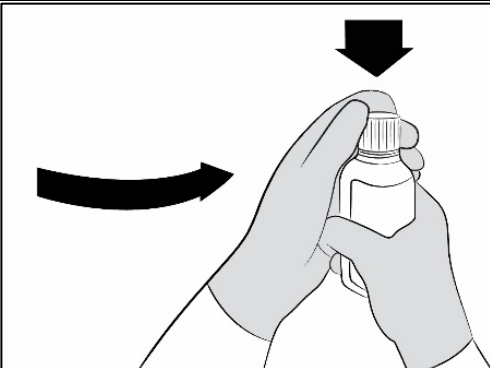
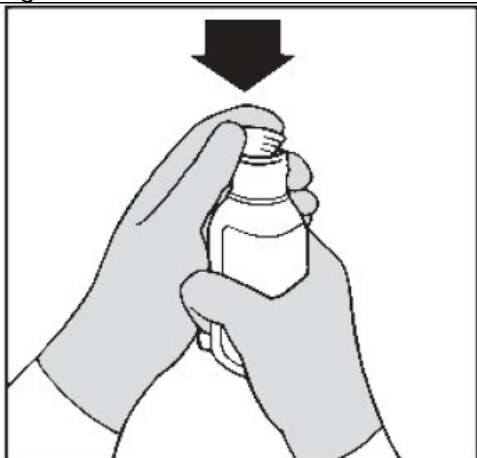
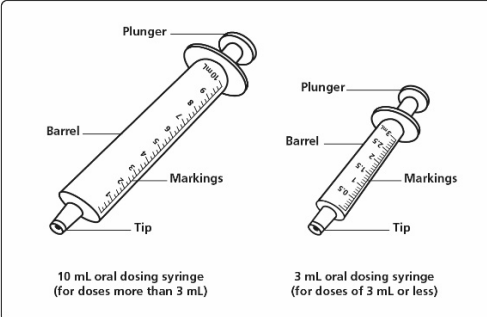
Each carton of XROMI oral solution contains:

- 1 bottle of XROMI oral solution
- 1 bottle adapter
- One 3 mL oral dosing syringe (for doses of 3 mL or less)
- One 10 mL oral dosing syringe (for doses more than 3 mL)



If your carton does not contain two oral dosing syringes, contact your pharmacist.

You will also need disposable gloves.

Before giving XROMI:	
Step 1. Wash your hands well with soap and water.	
Step 2. Put on disposable gloves.	
Step 3. Place the items from the carton on a clean flat surface.	
Step 4. Open the bottle by pushing down firmly on the child-resistant cap and turning it counter-clockwise (See Figure A). Do not throw away the child-resistant cap.	
Step 5. First time use only; Insert the bottle adapter. Push the ribbed end of the bottle adapter into the neck of the bottle until it is firmly in place. The bottom edge of the adapter should fully contact the top rim of the bottle (See Figure B). Do not remove the adapter from the bottle after it is inserted.	
Measuring your child's prescribed dose of XROMI:	
Step 6. Choose the oral dosing syringe you need to measure your child's prescribed dose (See Figure C). Check the dose in mL as prescribed by your child's healthcare provider. Choose the right oral dosing syringe for your child's dose. <ul style="list-style-type: none"> • Use the 3 mL oral dosing syringe for doses of 3 mL or less. • Use the 10 mL oral dosing syringe for doses more than 3 mL. 	
Find the marking for your child's prescribed dose on the right oral dosing syringe.	Figure C
Step 7. Push the plunger of the oral dosing syringe all the way down to remove any air in the oral dosing syringe (see Figure D).	

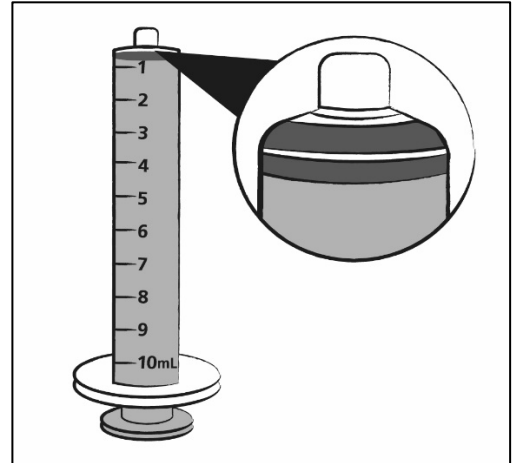


Figure D

Step 8. Hold the bottle upright. Insert the tip of the oral dosing syringe into the opening of the bottle adapter until it is firmly in place (See Figure E).

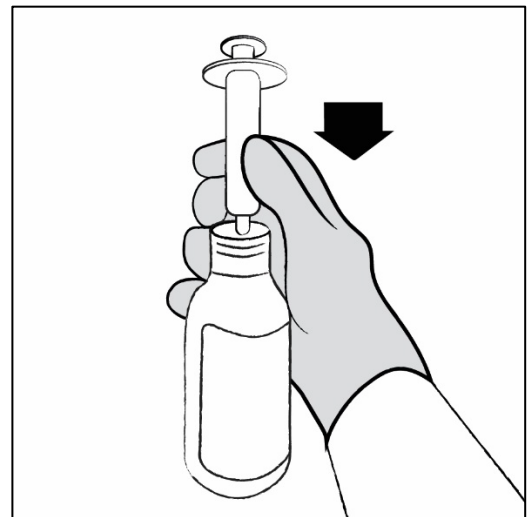


Figure E

Step 9. Turn the bottle upside down with the oral dosing syringe in place. Pull back slowly on the plunger of the oral dosing syringe until the top of the plunger is even with the mL mark on the oral dosing syringe that corresponds to your child's prescribed dose.

See Figure F for an **example** of a dose of 6 mL. Your dose may be different than the example shown.

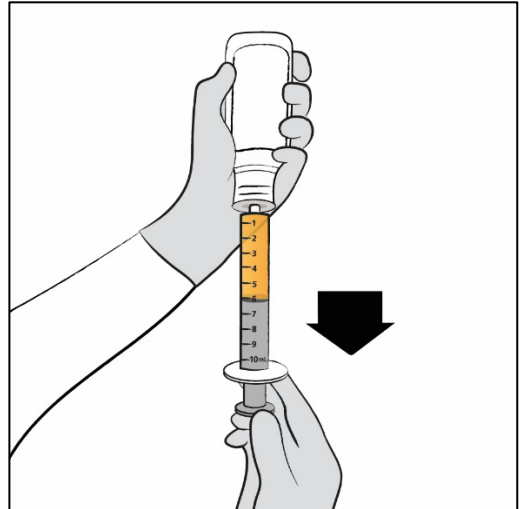


Figure F

Step 10. Leave the oral dosing syringe in the bottle adapter and turn the bottle upright. Place the bottle onto a flat surface. Hold the oral dosing syringe by the barrel and carefully remove it from the adapter. **Do not** hold the oral dosing syringe by the plunger (See Figure G).

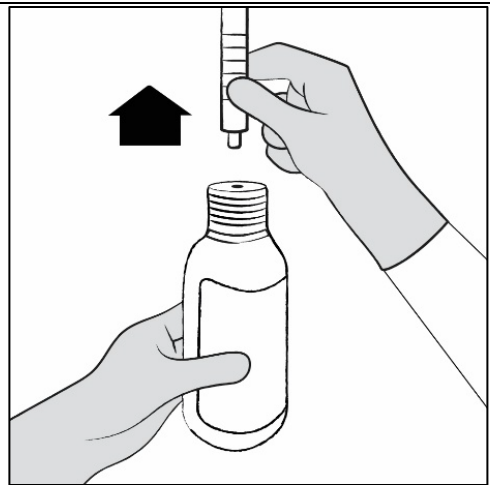


Figure G

Step 11. Hold the oral dosing syringe with the oral dosing syringe tip pointing up. Check that the correct dose was drawn up into the oral syringe (See Figure H).

If there are large air bubbles in the oral dosing syringe (See Figure I) or if you have drawn up the wrong dose, re-insert the oral dosing syringe tip firmly into the bottle adapter while the bottle is in an upright position. Fully push in the plunger so the oral solution flows back into the bottle. Repeat Steps 8 and 9.

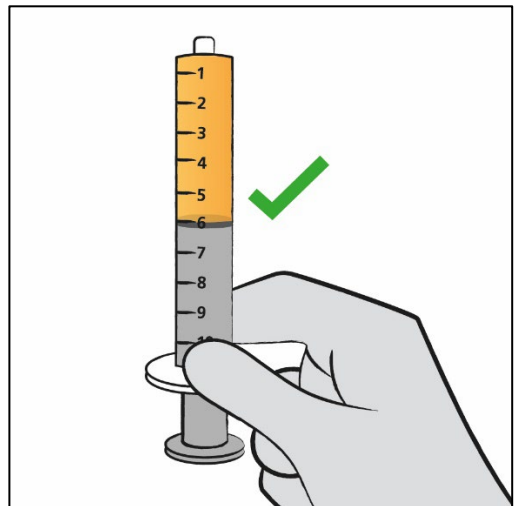
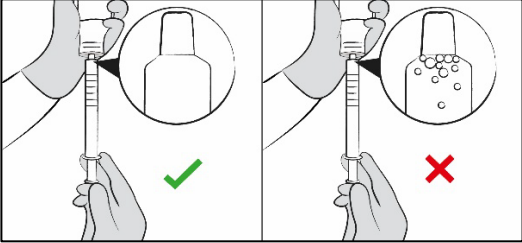
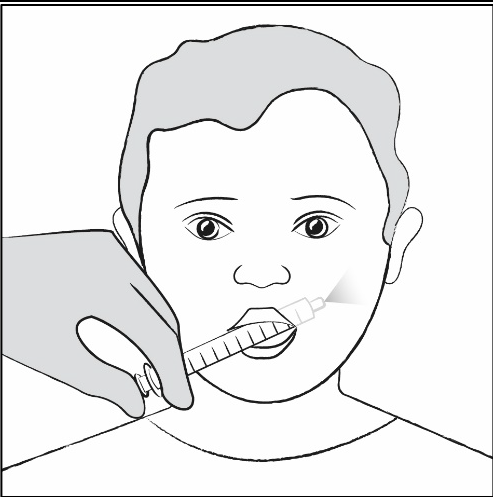


Figure H

	 <p>Figure I</p>
<p>Giving the prescribed dose of XROMI:</p> <p>Step 12. Place the tip of the oral dosing syringe in your child's mouth and place the tip against the inside of your child's cheek. Gently push the plunger all the way down to give all the medicine in the oral dosing syringe and then remove the oral dosing syringe from your child's mouth (See Figure J).</p> <p>Make sure the child has time to swallow the medicine.</p> <p>If your child's prescribed dose is more than 10 mL, you will need to divide the dose. Follow the instructions given to you by your healthcare provider or pharmacist about how to divide the dose and repeat Steps 6 through 12.</p>	 <p>Figure J</p>
<p>Step 13. Have your child drink some water to make sure no medicine is left in your child's mouth.</p>	
<p>Step 14. Close the bottle tightly by turning the child-resistant cap clockwise, leaving the bottle adapter in place.</p>	
<p>Step 15. Wash your hands well with soap and water. Rinse and wash the oral dosing syringes with cold or warm water and dry completely before next use. Hold the oral dosing syringe under water and move the plunger up and down several times to make sure the inside of the oral dosing syringe is clean. Let the oral dosing syringe dry completely before you use it again. Do not throw away the oral dosing syringe after use.</p>	

Storing XROMI

- Store XROMI in a refrigerator between 35°F to 46°F (2°C to 8°C). **Do not freeze.**
- Store the XROMI bottle and oral dosing syringe in a clean place.
- XROMI oral solution should be used within 12 weeks after opening the bottle. Dispose of (throw away) any unused medicine and the dosing syringes after 12 weeks.
- Do not use after the expiration date on the carton and the bottle.
- **Keep XROMI and all medicines out of the reach of children.**

Disposing of XROMI

- Ask your pharmacist for instructions on how to throw away (dispose of) XROMI that is expired or no longer needed.

Manufactured by: Nova Laboratories, Ltd., Leicester LE18 4YL, United Kingdom
Manufactured for: Rare Disease Therapeutics, Inc. 2550 Meridian Blvd., Suite 150
Franklin, TN 37067
Part Number: D001426/1

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised:
12/2024