

INSTRUCTIONS FOR USE

EVERYSDI® [ev-RIZ-dee]

(risdiplam)

Tablets, for oral use

Before you start

This Instructions for Use contains information on how to prepare and take EVERYSDI tablets.

Read this Instructions for Use and Patient Information leaflet before you start taking or giving EVERYSDI tablets for the first time and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. If you have any questions about how to take EVERYSDI, contact your healthcare provider.

Important Information

- If you are taking EVERYSDI tablets, the daily dose is one tablet.
- EVERYSDI tablets can be swallowed whole with water. Do not chew, cut, or crush the tablet.
- If you are unable to swallow EVERYSDI tablets whole or have a nasogastric (NG) tube or gastrostomy tube (G-tube), your healthcare provider will show you how to prepare and take EVERYSDI tablets. Always take EVERYSDI tablets exactly as your healthcare provider tells you.
- **Do not** take or give EVERYSDI tablets until you have been shown the right way to prepare and take or give EVERYSDI.
- Wash your hands before and after preparing, taking or giving EVERYSDI.
- Check the expiration date and check the product for damage before use. Do not use if expired or damaged.
- **Avoid** getting the EVERYSDI tablet mixture on your skin or in your eyes. If the EVERYSDI tablet mixture gets on your skin, wash the area with soap and water. If the tablet mixture gets in your eyes, rinse your eyes with water.
- Keep the EVERYSDI tablet mixture out of sunlight.
- If you spill the EVERYSDI tablet mixture, dry the area with a dry paper towel and then clean with soap and water. Throw away the paper towel in the trash and wash your hands with soap and water.
- **Do not** take an extra dose if you vomit at any time after taking EVERYSDI.

How to store EVERYSDI tablets

- Store EVERYSDI tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- Do not take or give EVERYSDI if it has been exposed to temperatures above 86°F (30°C).
- Keep tablets in the original bottle. Keep the bottle tightly closed to protect from moisture.
- Keep EVERYSDI and all medicines out of the sight and reach of children.

If able to swallow the EVRYSDI tablet whole:

Swallow the tablet whole with water.

Do not chew, cut, or crush the tablet.

Do not swallow with any liquids other than water.

Wash your hands with soap and water

If unable to swallow the EVRYSDI tablet whole:

Prepare an EVRYSDI tablet mixture

Gather supplies

(Figure A):

- 1 EVRYSDI tablet
- a small, clean empty cup
- 1 teaspoon (5 mL) of room temperature non-chlorinated drinking water (such as filtered water) for mixing
- at least 1 tablespoon (15 mL) of non-chlorinated drinking water (such as filtered water) for rinsing
- If giving EVRYSDI through a feeding tube: 1 dosing syringe that connects to the feeding tube

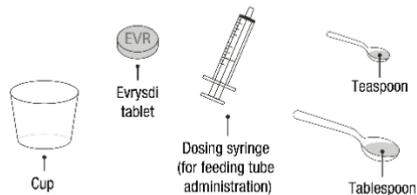


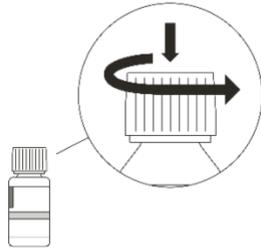
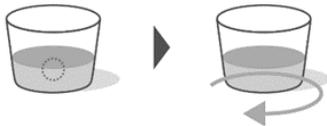
Figure A

The cup and the dosing syringe are not included in the package. Obtain a dosing syringe from your healthcare provider or pharmacist. Your healthcare provider or pharmacist can help you choose the right dosing syringe.

Step 1. Wash your hands with soap and water **(Figure B).**



Figure B

<p>Step 2. Remove the cap by pushing down and then twisting the child resistant cap to the left (counterclockwise) (Figure C).</p>	 <p style="text-align: center;">Figure C</p>
<p>Step 3. Take 1 tablet out of the bottle (Figure D).</p>	<p style="text-align: center;">1x </p> <p style="text-align: center;">Figure D</p>
<p>Step 4. Replace the child resistant cap on the bottle, turn the cap to the right (clockwise) until tightly closed. (Figure E).</p> <p>Do not store EVRYSDI outside the original container due to moisture sensitivity.</p>	 <p style="text-align: center;">Figure E</p>
<p>Step 5 Put 1 teaspoon (5 mL) of room temperature non-chlorinated drinking water (such as filtered water) in a small cup and add 1 tablet.</p> <ul style="list-style-type: none"> • Do not use any liquids other than non-chlorinated drinking water (such as filtered water). • Do not expose the mixture to sunlight. 	 <p style="text-align: center;">Figure F</p>
<p>Step 6 Gently swirl the cup until it is fully mixed. Some particles may remain after swirling. This may take up to 3 minutes. (Figure F).</p>	
<p>Option A: To take or give the tablet mixture by mouth, see Step A1 Option B: To take or give the tablet mixture by feeding tube, see Step B1</p>	

Option A: Take or give EVRYSDI tablet mixture by mouth

Step A1

Drink or give the tablet mixture right away. Throw away the mixture if not used within 10 minutes of adding the tablet to the cup with non-chlorinated drinking water (such as filtered water) (**Figure G**).



Figure G

Step A2

Refill the cup with at least 1 tablespoon (15 mL) of non-chlorinated drinking water (such as filtered water) and swirl to get any medicine left in the cup (**Figure H**).

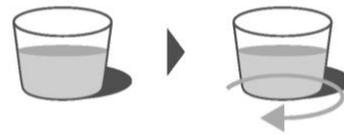


Figure H

Step A3

Drink the 2nd mixture right away. (**Figure I**).



Figure I

Step A4

Wash your hands and all the items used to give EVRYSDI (**Figure J**).

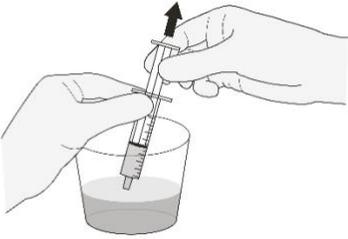
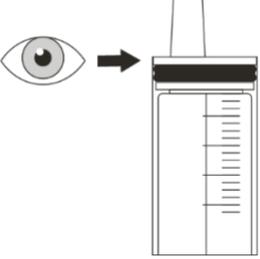


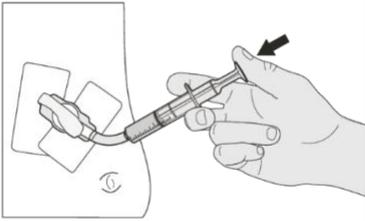
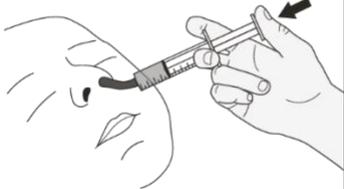
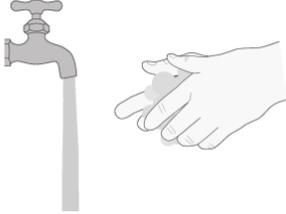
Figure J

Option B: Take or give EVRYSDI tablet mixture through a feeding tube (gastrostomy or nasogastric tube)

You can take or give the EVRYSDI tablet mixture through a feeding tube (gastrostomy or nasogastric tube) placed by a healthcare provider.

Check the manufacturer's instructions for the size and dimensions of the gastrostomy or nasogastric tube. **Make sure that the gastrostomy or nasogastric tube size is at least 8 French or higher to prevent clogging of the feeding tube. Ask your healthcare provider to show you how to check the feeding tube before giving EVRYSDI.**

<p>Step B1</p> <p>Take or give EVRYSDI tablet mixture right away. Throw away the mixture if not used within 10 minutes of adding the tablet to the cup with non-chlorinated drinking water (such as filtered water).</p> <p>Place the dosing syringe tip into the cup and slowly pull up the plunger to draw up all the mixture (Figure K).</p>	 <p style="text-align: center;">Figure K</p>	
<p>Step B2</p> <p>Place the dosing syringe tip into the gastrostomy or nasogastric tube. Slowly push the plunger all the way down to give the full dose of EVRYSDI (Figure L1 or L2).</p>	 <p style="text-align: center;">Figure L1 (gastrostomy tube)</p>	 <p style="text-align: center;">Figure L2 (nasogastric tube)</p>
<p>Step B3</p> <p>Check that there is no EVRYSDI left in the dosing syringe (Figure M).</p>	 <p style="text-align: center;">Figure M</p>	
<p>Step B4</p> <p>Refill the cup with at least 1 tablespoon (15 mL) of non-chlorinated drinking water (such as filtered water) and swirl to get any medicine left in the cup (Figure N).</p> <p>Place the dosing syringe into the cup and pull up the plunger to draw up all the mixture.</p>	 <p style="text-align: center;">Figure N</p>	

<p>Step B5</p> <p>Flush the gastrostomy or nasogastric tube with the mixture (Figure O1 or O2).</p>	 <p>Figure O1 (gastrostomy tube)</p>	 <p>Figure O2 (nasogastric tube)</p>
<p>Step B6</p> <p>Wash your hands and all the items used to give EVRYSDI (Figure P).</p> <p>Check with your pharmacist if the dosing syringe provided is for single use only or can be re-used multiple times. Follow the manufacturer's instructions to throw away or immediately clean your dosing syringe.</p>	 <p>Figure P</p>	

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

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