

Instructions For Use – Administration

Evrysdi®

(risdiplam) film-coated tablets

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

- The information in this Instructions for Use is for taking or giving this medicine – but here we just say ‘take’.

Before you start

Read this Instructions for Use before taking Evrysdi film-coated tablets for the first time and each time you get a refill. There may be new information.

Evrysdi film-coated tablets can be taken by:

- **Option A: swallowing whole by mouth, or**
- **Option B: mixed with a small amount of room temperature non-chlorinated drinking water (e.g. bottled water) and taken by mouth, or**
- **Option C: mixed with a small amount of room temperature non-chlorinated drinking water (e.g. bottled water) and given through a feeding tube (i.e., a nasogastric (NG tube) or gastrostomy (G tube) tube).**

Important Information

- Your doctor, pharmacist, or nurse will show you how to prepare and take Evrysdi tablets. Always take Evrysdi tablets exactly as your healthcare provider tells you.
- Do not take or give this medicine until you have been shown how to properly prepare and take Evrysdi.
- Wash your hands before and after preparing or taking Evrysdi.
- Check the expiry date and check the product for damage before use. Do not use if expired or damaged.
- Avoid getting the Evrysdi tablet mixture on your skin or in your eyes. If the Evrysdi 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 Evrysdi tablet mixture out of sunlight.
- If you spill the Evrysdi tablet mixture, dry the area with a dry paper towel and then clean with soap and water. Throw away the paper towel in the rubbish and wash your hands with soap and water.

How to take Evrysdi tablets

- If you are taking Evrysdi tablets, the daily dose is 1 tablet.
- Take the tablet whole with water or as a liquid by mixing 1 tablet in at least 1 teaspoon (5 ml) of room temperature non-chlorinated drinking water (e.g. bottled water) at the same time each day.
- **Do not** chew, cut, or crush the tablet.
- **Do not** mix Evrysdi with any liquids other than non-chlorinated drinking water (e.g. bottled water).
- **Do not** take Evrysdi tablet mixture if it has been more than 10 minutes since adding water to the tablet. Throw the mixture away according to your local requirements and make a new dose.

- **Do not** take an extra dose if you are sick (vomit) at any time after taking Evrysdi.

Get ready to take an Evrysdi tablet

Step 1. Wash your hands. (**Figure A**).

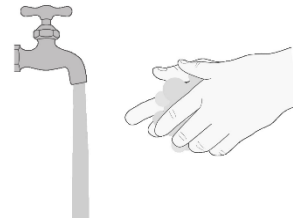


Figure A

Step 2. Take out 1 Evrysdi tablet from the blister (**Figure B**).



Figure B

option A: Swallow the Evrysdi tablet whole

Step A1

Swallow the tablet whole with some water.

Do not chew, cut, or crush the tablet

Do not swallow with any liquids other than water.

Step A2

Wash your hands with soap and water.

option B: Take Evrysdi tablet mixed in non-chlorinated drinking water (e.g. bottled water)

What is needed to mix Evrysdi with non-chlorinated drinking water (e.g. bottled water):

- 1 Evrysdi tablet
- a small, clean empty cup
- at least 1 teaspoon (5ml) of room temperature non-chlorinated drinking water (e.g. bottled water) for mixing
- at least 1 tablespoon (15ml) of non-chlorinated drinking water (e.g. bottled water) for rinsing

Step B1

Put at least 1 teaspoon (5ml) of non-chlorinated drinking water (e.g. bottled water) in a cup – and add 1 tablet.

- **Do not** use any liquids other than non-chlorinated drinking water (e.g. bottled water),
- Keep the mixture out of sunlight.

Step B2

Gently swirl the cup until it is fully mixed - this can take up to 3 minutes (**Figure C**).

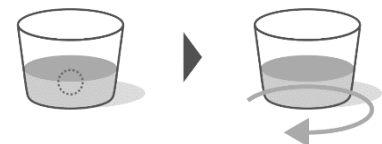


Figure C

To take by mouth see Step C1
To take by feeding tube see Step D1

Take Evrysdi by mouth

Step C1

Drink immediately within 10 minutes of adding non-chlorinated drinking water (e.g. bottled water) to the tablet (**Figure D**).



Figure D

Step C2

Refill the cup with at least 1 tablespoon (15ml) of non-chlorinated drinking water (e.g. bottled water) and swirl to get any medicine left in the cup (**Figure E**).

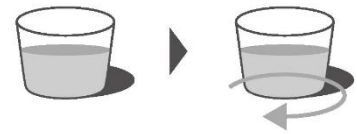


Figure E

Step C3

Drink immediately (**Figure F**).

Go to Step E1 for clean-up instructions.



Figure F

Option C: Administration through a gastrostomy or nasogastric tube

You can take or give the mixture through a nasogastric or gastrostomy tube placed by the healthcare professional. Check the manufacturer's instructions for the size and dimensions of the enteral tube. Make sure that the tube size is at least 8 French or higher to prevent clogging of the tube.

Step D1

Administer immediately within 10 minutes of adding non-chlorinated drinking water (e.g. bottled water) to the tablet.

Place the syringe tip right away into the cup and slowly pull up the plunger to draw up all the mixture (**Figure G**).

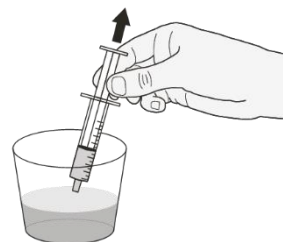
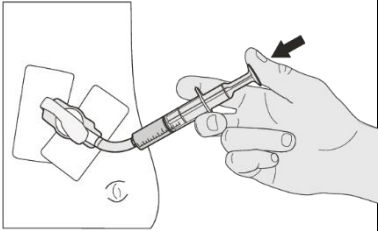
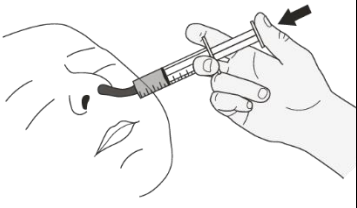
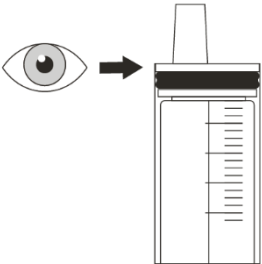
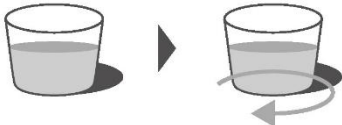
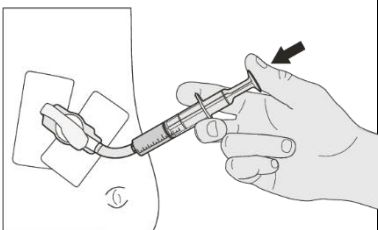
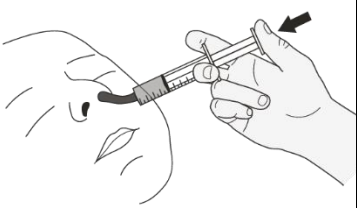


Figure G

Step D2 Place the syringe tip into the nasogastric/gastrostomy tube. Slowly press the plunger all the way down to give the full dose of Evrysdi (Figure H1 and H2).	 Figure H1	 Figure H2
Step D3 Check that there is no medicine left in the syringe (Figure I).	 Figure I	
Step D4 Refill the cup with at least 1 tablespoon (15ml) of non-chlorinated drinking water and swirl to get any medicine left in the cup (Figure J). Place the syringe into the cup and pull up the plunger to draw up all the mixture.	 Figure J	
Step D5 Flush the gastrostomy or nasogastric tube with the mixture (Figure K1 and K2). Go to Step E1 for clean-up instructions.	 Figure K1	 Figure K2

After administering

Step E1

Wash your hands and all the items used to give Evrysdi.

Storing Evrysdi

- Store Evrysdi tablet below 30°C.
- Keep in the original package to protect from moisture.
- Keep Evrysdi and all medicines out of the sight and reach of children.

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