

Instructions For Constitution (for HCP)

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**Evrysdi 0.75 mg/mL**

**Powder for oral solution**

Risdiplam

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Instructions for Constitution  
**(FOR PHARMACISTS ONLY)**

**Each Evrysdi carton contains (See figure A):**

- ❶ 1 Cap
- ❷ 1 Evrysdi bottle
- ❸ 2 Oral syringes 12 mL (in pouches)
- ❹ 2 Oral syringes 6 mL (in pouches)
- ❺ 1 Press-in bottle adapter
- ❻ 1 Package Leaflet (not shown)
- ❼ 1 Instructions for Constitution (not shown)
- ❽ 1 Instructions for Use (not shown)

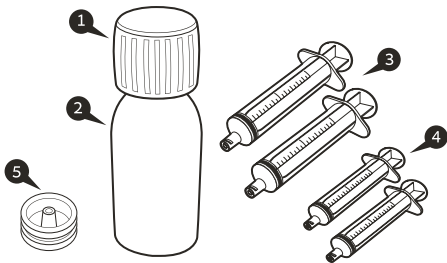


Figure A

## Important information about Evrysdi

- **Avoid inhaling** Evrysdi powder.
- **Use gloves.**
- **Do not** use if the powder expiry date has passed. The powder expiration date is printed on the bottle label.
- **Do not** dispense the constituted solution if the solution's Discard After date exceeds the original powder expiration date.
- **Avoid getting contact** with the medicine on your skin. If the medicine gets on your skin, wash the area with soap and water.
- **Do not** use the medicine if any of the supplies are damaged or missing.
- Use Purified Water or Water for Injection to constitute the medicine.
- Do not add oral syringes other than the ones provided in the carton.

## **How to store Evrysdi**

- Do not store the powder (unconstituted medicine) above 25°C and keep it in the carton. Do not freeze.
- Store the solution (constituted medicine) in a refrigerator (2 to 8°C) and keep it in the carton upright.
- Keep the oral solution in the original bottle and always keep the bottle in an upright position with the cap tightly closed.

## Constitution

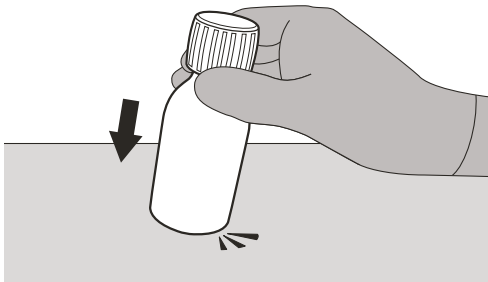


Figure B

### Step 1

Gently tap the bottom of the bottle to loosen the powder (See Figure B).

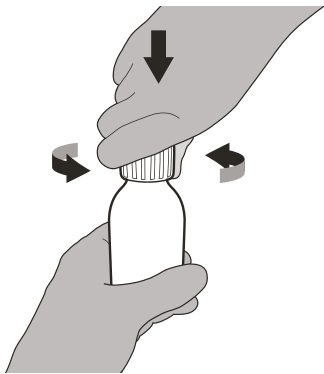


Figure C

## Step 2

Remove the cap by pushing it down and then twisting to the left (counter-clockwise) (See Figure C). Do not throw away the cap.



Figure D

### Step 3

Carefully pour 79 mL of Purified Water or Water for Injection into the medicine bottle (See Figure D).



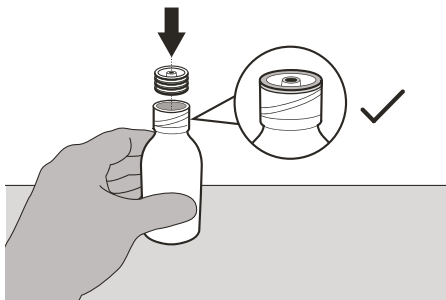


Figure E

#### Step 4

Hold the medicine bottle on a table with one hand.

Insert the press-in bottle adapter into the opening by pushing it down with the other hand. Ensure it is completely pressed against the bottle lip (See Figure E).

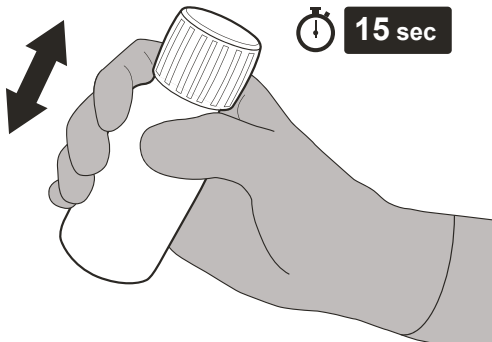


Figure F

### Step 5

Put the cap back on the bottle. Turn the cap to the right (clockwise) to close the bottle.

Ensure it is completely closed and then shake well for 15 seconds (See Figure F).

Wait for 10 minutes. You should have obtained a **clear solution**.

Afterwards, shake well again for another 15 seconds.

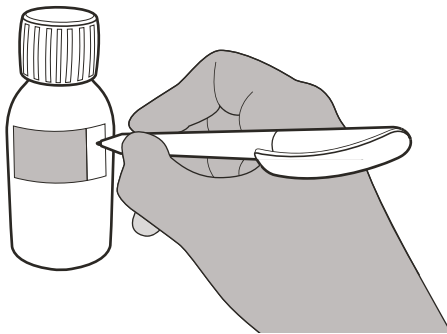


Figure G

### Step 6

Calculate the Discard After date as **64 days** after constitution (Note: the day of constitution is counted as day 0. For example, if constitution is on the 1<sup>st</sup> of April, the Discard After date will be the 4<sup>th</sup> of June).

**Write the Discard After date** of the solution on the bottle label (See Figure G) and carton.

Put the bottle back in its original carton, with syringes (in pouches), patient leaflet and Instructions For Use booklet. Store the carton in the refrigerator (2 to 8°C).

**MARKETING AUTHORISATION HOLDER**

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**MARKETING AUTHORISATION NUMBER(S)**

167-71-36630-99

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