

**EVRYSDI®**  
(risdiplam) for oral solution

Instructions for Constitution  
**(FOR HEALTHCARE PROVIDERS ONLY)**

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

- ① 1 Cap
- ② 1 EVRYSDI bottle
- ③ 1 Reusable oral syringe 12 mL
- ④ 2 Reusable oral syringes 6 mL
- ⑤ 2 Reusable oral syringes 1 mL
- ⑥ 1 Press-in bottle adapter
- ⑦ 1 Prescribing Information (not shown)
- ⑧ 1 Instructions for Constitution (not shown)
- ⑨ 1 Instructions for Use (not shown)

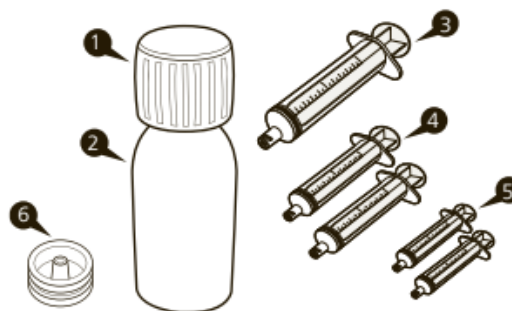


Figure A

**Important information about EVRYSDI**

- **Do not** use if the powder expiration date has passed. The powder expiration date is printed on the bottle label.
- **Do not** use the medicine if any of the supplies are damaged or missing.
- Use purified water to constitute the medicine.
- Select the appropriate oral syringes (1 mL, 6 mL, or 12 mL) based on the patient's dose and provide instruction to the patient/caregiver on how to administer their dose. The oral syringes provided in the carton are intended to be reusable.
- Only use the amber oral syringe provided for use with EVRYSDI. Other syringes may not be compatible with the press-in-bottle adapter and may not protect the product from light.

**How to store EVRYSDI**

- Store the dry powder at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled room temperature]. Keep in the original carton.
- Store the constituted oral solution of EVRYSDI upright in the original amber bottle in a refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze.

## Important precautions for preparation of EVRYSDI

- **Avoid inhalation and direct contact** with skin or mucous membranes with the dry powder and the constituted solution. If such contact occurs, wash thoroughly with soap and water; rinse eyes with water.
- **Wear disposable gloves** during the preparation and clean up procedure.

## Constitution

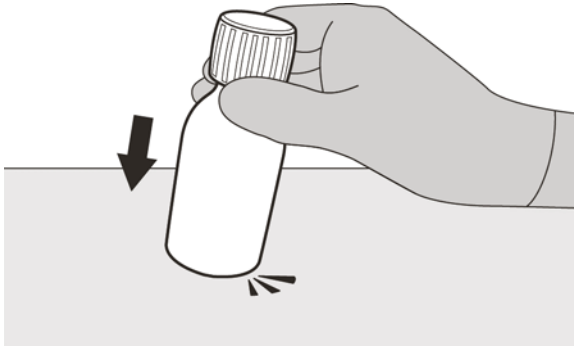


Figure B

### Step 1

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

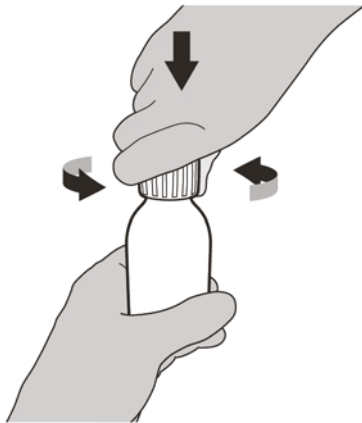


Figure C

### 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.

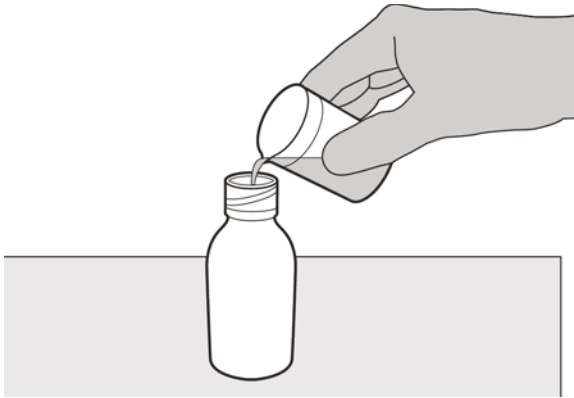


Figure D

### Step 3

Carefully pour 79 mL of purified water into the medicine bottle (See Figure D).

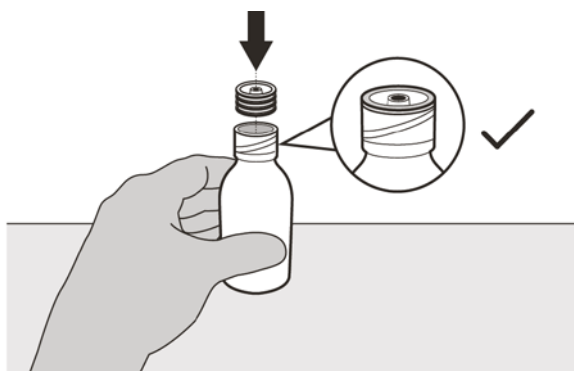


Figure E

### 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).

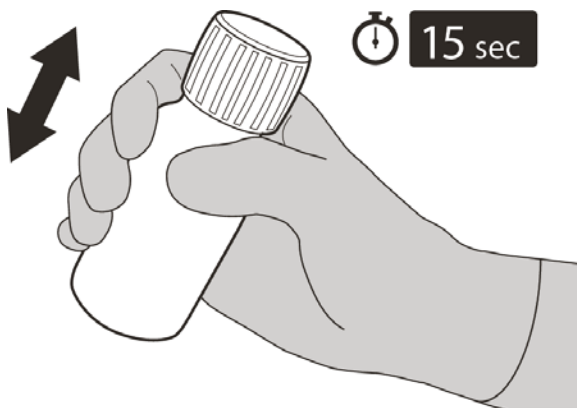


Figure F

### 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**.

If not, shake well again for another 15 seconds.

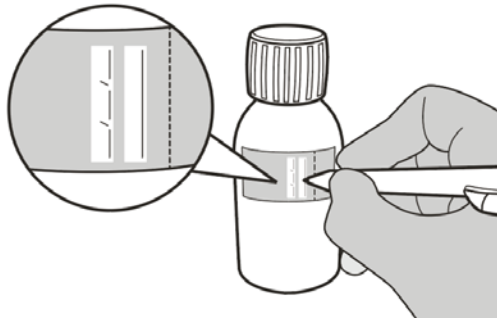


Figure G

### Step 6

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

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

Do not dispense the constituted solution if the solution's Discard After date exceeds the original powder expiration date.

### Step 7

Remove and discard the peel-off part of the bottle label with the expiration date of the powder (See Figure H).

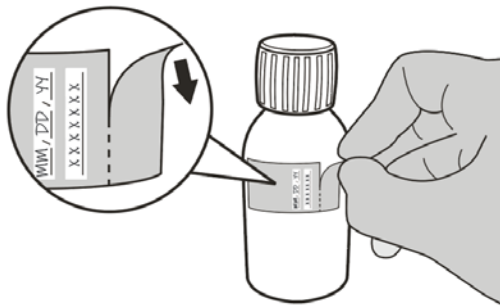


Figure H

## Selecting the oral syringe for the prescribed daily dose of EVRYSDI

For the calculation of dosing volume, the syringe increments need to be considered. Round the dose volume to the closest increment marked on the selected oral syringe.

Select the correct oral syringe(s) (1 mL, 6 mL, or 12 mL) for the calculated dosing volume according to the table below and remove the other oral syringes.

Dose Strength	Syringe Size	Dosing Volume	Syringe Increments
0.75 mg/mL	1 mL	0.3 mL to 1 mL	0.01 mL
	6 mL	1 mL to 6 mL	0.1 mL
	12 mL	6.2 mL to 6.6 mL	0.2 mL

Put the bottle back in its original carton with the correct oral syringes, Prescribing Information, and Instructions for Use.

Store the constituted oral solution of EVRYSDI upright in the original amber bottle in a refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze. Discard any unused portion 64 days after constitution.

EVRYSDI is a registered trademark of Genentech, Inc.

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**Genentech, Inc.**  
 1 DNA Way

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