

Instructions For Reconstitution (750 microgram/mL)

Evrysdi®

(risdiplam) for oral solution

Instructions for Reconstitution

(FOR HEALTHCARE PROFESSIONALS/PHARMACISTS ONLY)

Each Evrysdi carton contains (See figure A):

1. 1 Cap
2. 1 Evrysdi bottle
3. 1 Oral syringes 12 mL (in a pouch)
4. 2 Oral syringes 6 mL (in pouches)
5. 2 Oral syringes 1 mL (in pouches)
6. 1 Press-in bottle adapter
7. 1 "Instructions for Reconstitution" (not shown)
8. 1 "Instructions for Use – Administration" (not shown)

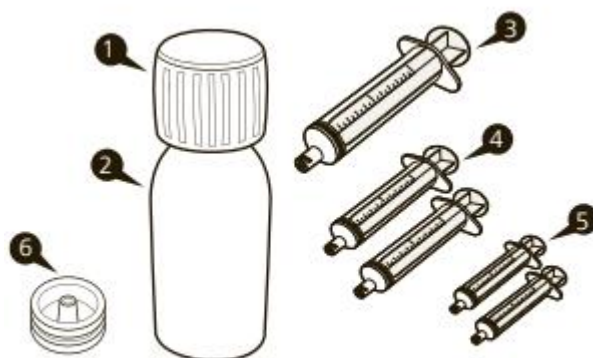


Figure A

Important precautions for preparation of Evrysdi

- **Caution** should be exercised during handling.
- **Avoid inhalation** and avoid direct contact with skin or mucous membranes with the dry powder and the reconstituted solution.
- **Use gloves** during reconstitution and while wiping the outer surface of the bottle/cap and cleaning the working surface after reconstitution.
- **Avoid contact** with the medicine on your skin. If the medicine gets on your skin, wash the area with soap and water.

Important information about Evrysdi

- **Do not** use if the powder expiry date has passed. The powder expiry date is printed on the carton and bottle label.
- **Do not** dispense the reconstituted solution if the solution's "Discard Contents After" date exceeds the original powder expiry date.
- **Do not** use the medicine if any of the supplies are damaged or missing.
- Use Purified Water or Water for Injections (WFI) to reconstitute the medicine.
- Do not add oral syringes other than the ones provided in the carton.

How to store Evrysdi

- Store the powder (unreconstituted medicine) at below 25°C and keep it in the carton.
- Store the solution (reconstituted medicine) in a refrigerator between 2°C to 8°C (refrigerate, do not freeze).
- If necessary, the solution (reconstituted medicine) can be stored at room temperature (below 40°C) for no more than a total combined time of 5 days.
- Keep the oral solution in the original bottle and always keep the bottle in an upright position with the cap tightly closed.

Reconstitution

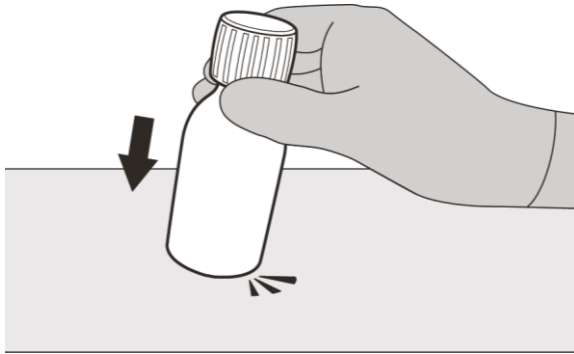


Figure B

Step 1

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

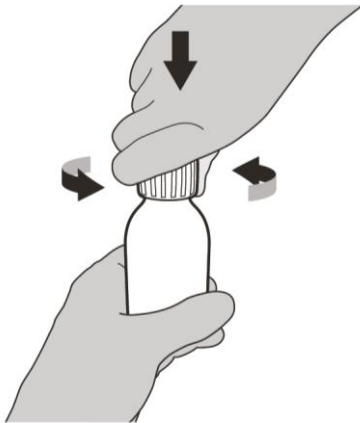


Figure C

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 Injections (WFI) into the medicine bottle (See Figure D).

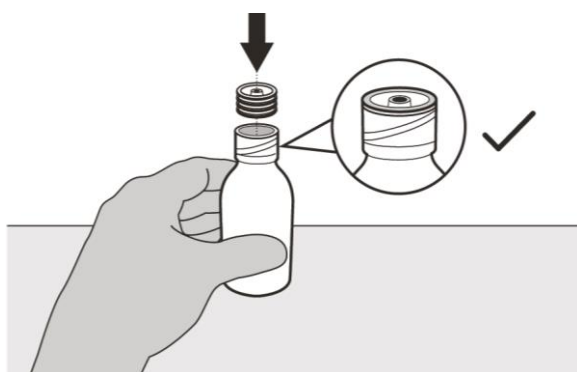


Figure E

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).

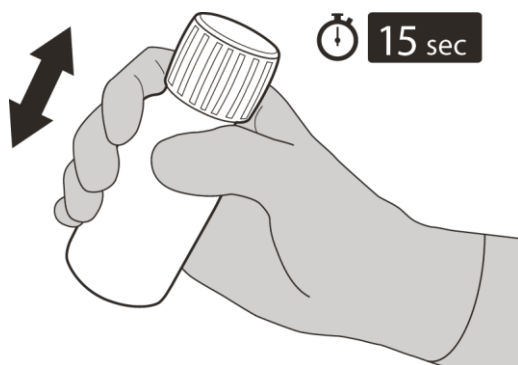


Figure F

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

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

Put the bottle back in its original carton, with syringes (in pouches), and "Instructions For Use – Administration" booklet. Store the carton in the refrigerator.

Selecting the oral syringe for the prescribed daily dose of Evrysdi

For the calculation of dosing volume, the syringe markings need to be considered. Round up or down the dose volume to the nearest graduation mark 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 Markings
0.75 mg/mL	1 mL	0.3 mL to 1.0 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

Evrysdi® (risdiplam)

Evrysdi is a trademark of Hoffmann-La-Roche AG.

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Instructions For Use – Administration (750 microgram/mL)

Evrysdi®

(risdiplam) for oral solution

Instructions for Use

Be sure to read and understand these **Instructions for Use** before you start using Evrysdi. The **Instructions for Use** provide information on how to prepare and give Evrysdi through an oral syringe, gastrostomy tube (G-tube), or nasogastric tube (NG-tube).

If you have any questions about how to use Evrysdi, contact your healthcare provider.

Evrysdi should come as a liquid in a bottle when you receive it. **Do not** use and contact your healthcare provider if the medicine in the bottle is a powder.

Important information about Evrysdi

- Ask your healthcare provider to show you how to measure your prescribed daily dose.
- See “**How to select the correct oral syringe to use for your prescribed dose volume of Evrysdi**” for the correct oral syringe you should use. Your healthcare provider will ensure the correct oral syringe is provided with your Evrysdi.
- Only use the re-usable oral syringes provided in the pack to measure your prescribed daily dose. The oral syringe protects the medicine from light.
- Contact your healthcare provider if your oral syringe(s) is lost or damaged. They will advise you on how to continue to take your medicine.
- If the bottle adapter is not in the bottle, **do not** use Evrysdi and contact your pharmacist.
- **Do not** use Evrysdi after the **Discard contents after** date written on the bottle label. Ask your pharmacist for the **Discard contents after** date if it is not written on the bottle label.
- **Do not** mix Evrysdi into food or liquids. Do not mix Evrysdi with formula or milk.
- **Do not** use Evrysdi if the bottle or oral syringe(s) are damaged.
- **Avoid** getting Evrysdi on your skin or in your eyes. If Evrysdi gets on your skin, wash the area with soap and water. If Evrysdi gets in your eyes, rinse your eyes with water.
- If you spill Evrysdi, dry the area with a dry paper towel and clean with soap and water. Throw away the paper towel in the waste and wash your hands well with soap and water.
- If there is not enough Evrysdi left in the bottle for your prescribed dose, use a new bottle to obtain your prescribed dose. **Do not mix** Evrysdi from the new bottle with the bottle you had been using. Return the used bottle with remaining Evrysdi to your pharmacist for safe disposal.

Each Evrysdi carton contains (See figure A):

- 1.** 1 Evrysdi bottle with bottle adapter and cap
- 2.** 1 Oral syringe 12 mL (in a pouch)
- 3.** 2 Oral syringes 6 mL (in pouches)
- 4.** 2 Oral syringes 1 mL (in pouches)
- 5.** 1 “Instructions for Use” leaflet (not shown)

Figure A

How to store Evrysdi

Store the oral solution in the refrigerator at 2°C to 8°C (refrigerate, do not freeze).

If necessary, you or your caregiver may store the oral solution at room temperature (below 40°C) for no more than a total combined time of 5 days.

Keep the oral solution in the original amber bottle to protect from light.

Keep the oral solution bottle in an upright position with the cap closed tightly.

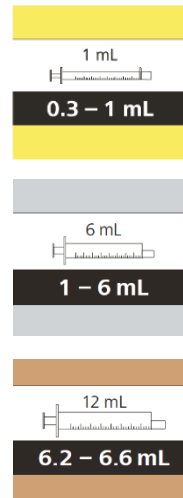
Keep it where young children cannot reach it.

Once transferred from the bottle to the oral syringe, use Evrysdi right away. Do not store the Evrysdi solution in the syringe.

A) Preparing and withdrawing your dose volume

How to select the correct oral syringe to use for your prescribed dose volume of Evrysdi

- If your prescribed daily dose of Evrysdi is between 0.3 mL and 1 mL, use a 1 mL oral syringe (yellow label).
- If your prescribed dose volume of Evrysdi is between 1 mL and 6 mL, use a 6 mL oral syringe (grey label).
- If your prescribed daily dose volume of Evrysdi is 6.2 mL or higher, use a 12 mL oral syringe (brown label).



Your healthcare provider will ensure the correct oral syringe is provided with your Evrysdi.

How to prepare your dose volume of Evrysdi

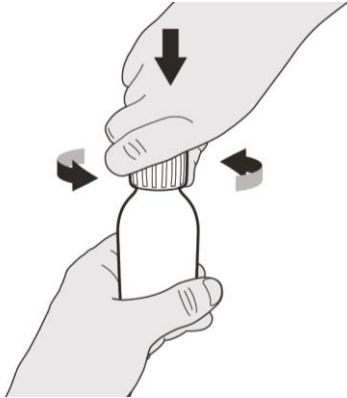


Figure B

Step A1

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

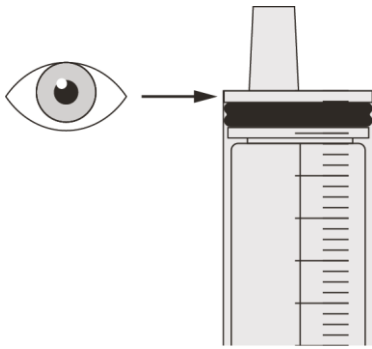


Figure C

Step A2

Push the plunger of the oral syringe all the way down to remove any air in the oral syringe (See Figure C).

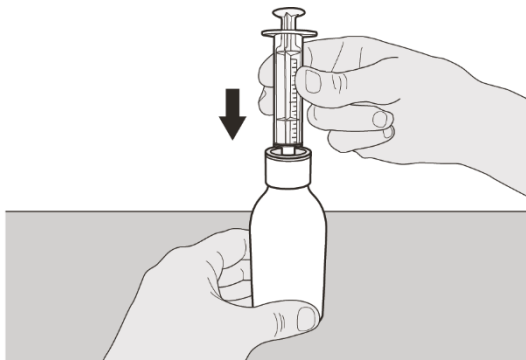


Figure D

Step A3

Keeping the bottle in an upright position, insert the syringe tip into the bottle adapter (See Figure D).

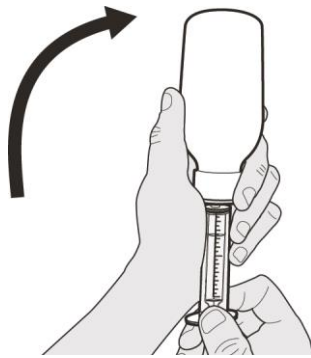


Figure E

Step A4

Carefully turn the bottle upside down with the syringe tip firmly inserted into the bottle adapter (See Figure E).

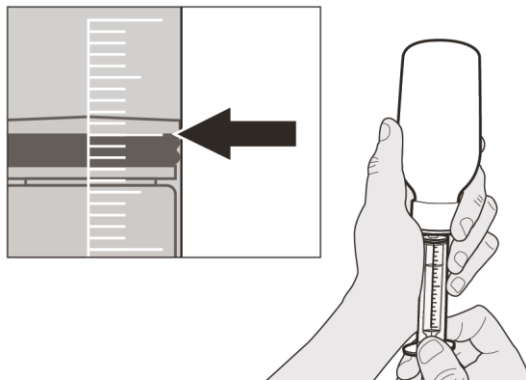


Figure F

Step A5

Slowly pull back on the plunger to withdraw your prescribed dose volume of Evrysdi. The top of the black plunger stopper must line up with the mL marking on the oral syringe for your prescribed daily dose volume (See Figure F).

After the correct dose is withdrawn, **hold the plunger in place to keep the plunger from moving.**

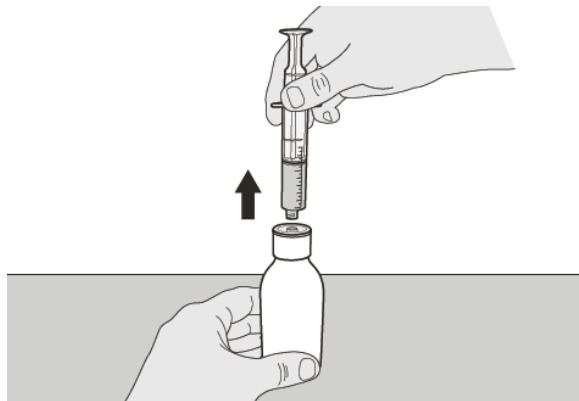


Figure G

Step A6

Continue to hold the plunger in place to keep the plunger from moving. Leave the oral syringe in the bottle adapter and turn the bottle to an upright position. Place the bottle onto a flat surface. Remove the oral syringe from the bottle adapter by gently pulling straight up on the oral syringe (See Figure G).

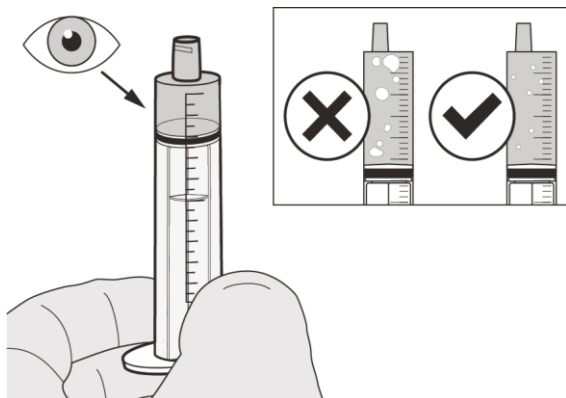


Figure H

Step A7

Hold the oral syringe with the syringe tip pointing up. Check the medicine in the oral syringe. **If there are large air bubbles in the oral syringe (See Figure H) or if you have drawn up the wrong dose volume of Evrysdi, insert the syringe tip firmly into the bottle adapter. Push the plunger all the way down so that the medicine flows back into the bottle and repeat Steps A4 through A7.**

Take or give Evrysdi immediately after it is drawn up into the oral syringe.

If it is not taken **within 5 minutes**, discard from oral syringe and prepare a new dose.

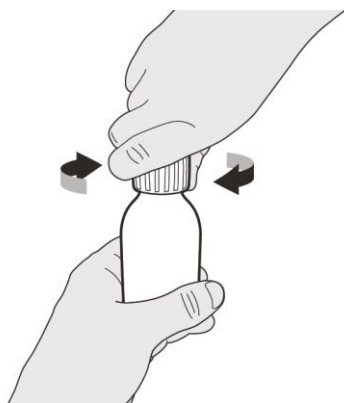


Figure I

Step A8

Put the cap back on the bottle. Turn the cap to the right (clockwise) to tightly close the bottle (See Figure I). Do not remove the bottle adapter from the bottle.

If you are taking your dose volume of Evrysdi by mouth, follow the instructions in **“B) How to take a dose volume of Evrysdi by mouth”**.

If you are taking your dose volume of Evrysdi through a gastrostomy tube, follow the instructions in **“C) How to give a dose volume of Evrysdi through a gastrostomy tube”**.

If you are taking your dose volume of Evrysdi through a nasogastric tube, follow the instructions in **“D) How to give a dose volume of Evrysdi through a nasogastric tube”**.

B) How to take a dose volume of Evrysdi by mouth

Sit upright when taking a dose volume of Evrysdi by mouth.



Figure J

Step B1

Place the oral syringe into the mouth **with the tip along either cheek**.

Slowly push the plunger all the way down to take the full dose of Evrysdi (See Figure J).

Giving Evrysdi into the throat or too fast may cause choking.

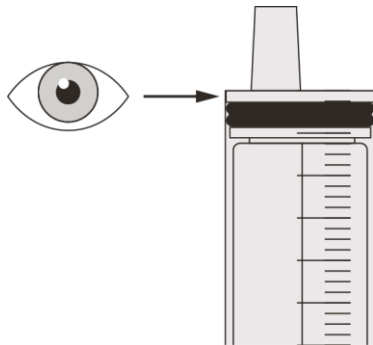


Figure K

Step B2

Check that there is no medicine left in the oral syringe (See Figure K).



Figure L

Step B3

Drink some water right after taking the prescribed dose of Evrysdi to ensure the medicine has been completely swallowed. (See Figure L).

Go to Step E for cleaning of the syringe.

C) How to give a dose volume of Evrysdi through a gastrostomy tube

If you are giving Evrysdi through a gastrostomy tube, ask your doctor to show you how to inspect the gastrostomy tube before giving Evrysdi.

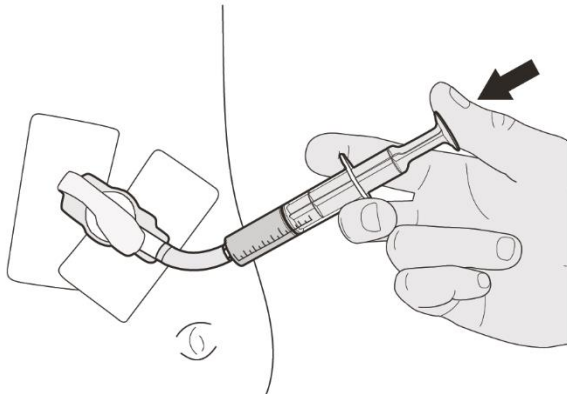


Figure M

Step C1

Place the oral syringe tip into the gastrostomy tube. Slowly push the plunger all the way down to give the full dose of Evrysdi (See Figure M).

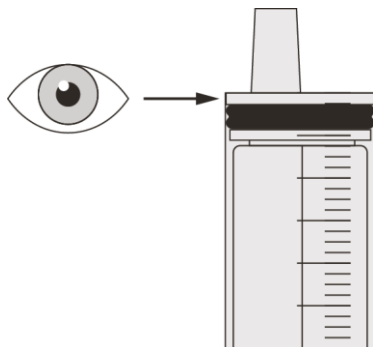


Figure N

Step C2

Check that there is no medicine left in the oral syringe (See Figure N).

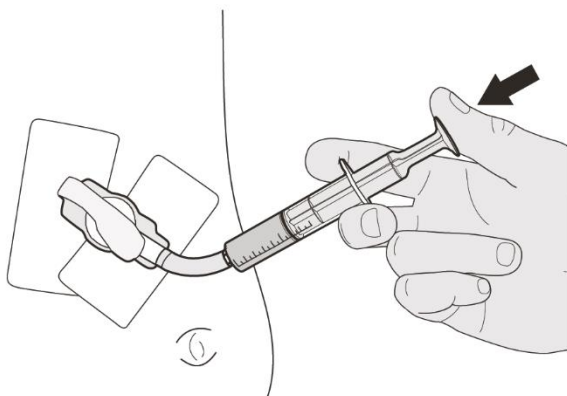


Figure O

Step C3

Flush the gastrostomy tube with 10-20 mL of water right after giving the prescribed dose of Evrysdi (See Figure O).

Go to Step E for cleaning of the syringe.

D) How to give a dose volume of Evrysdi through a nasogastric tube

If you are giving Evrysdi through a nasogastric tube, ask your doctor to show you how to inspect the nasogastric tube before giving Evrysdi.

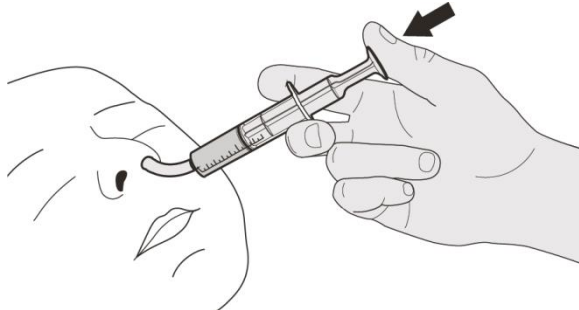


Figure P

Step D1

Place the oral syringe tip into the nasogastric tube. Slowly press the plunger all the way down to give the full dose of Evrysdi (See Figure P).

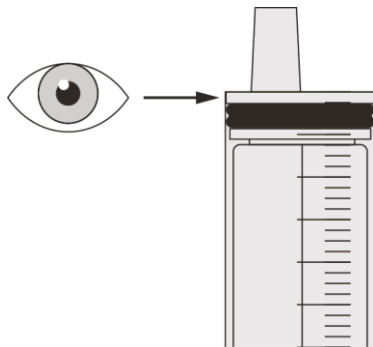


Figure Q

Step D2

Check that there is no medicine left in the oral syringe (See Figure Q).

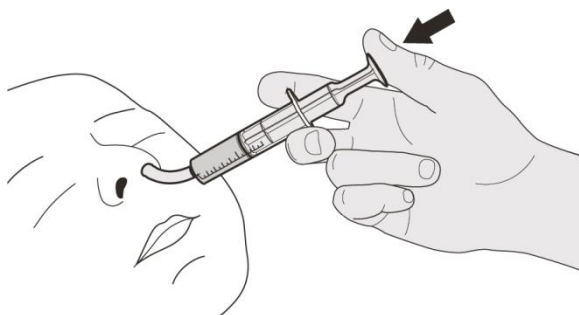


Figure R

Step D3

Flush the nasogastric tube with 10-20 mL of water right after giving the prescribed dose of Evrysdi (See Figure R).

Go to Step E for cleaning of the syringe.

E) How to clean the oral syringe after use

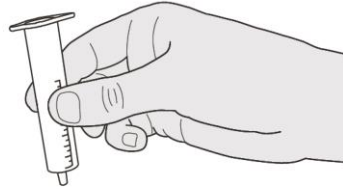
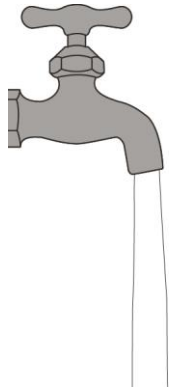


Figure S

Step E1

Remove the plunger from the oral syringe.

Rinse the oral syringe barrel well under clean water (See Figure S).

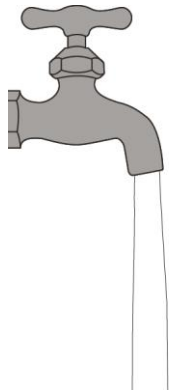


Figure T

Step E2

Rinse the plunger well under clean water (See Figure T).

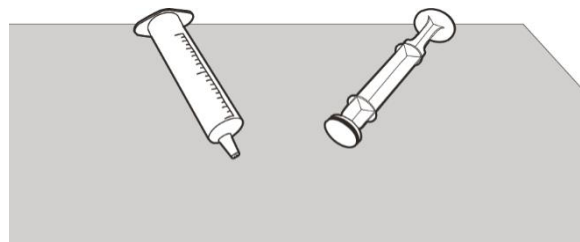


Figure U

Step E3

Check that the oral syringe barrel and plunger are clean.

Place the oral syringe barrel and plunger on a clean surface in a safe place to dry (See Figure U).

Wash your hands.

Once dry, reassemble the plunger into the oral syringe barrel and store the syringe with your medicine.

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