

EVERYSID[®] POWDER FOR ORAL SOLUTION

Risdiplam (0.75 mg/mL)

What is in this leaflet

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What EVRYSDI is used for

EVRYSDI is a prescription medicine used to treat spinal muscular atrophy (SMA) in children and adults.

How EVRYSDI works

EVRYSDI works by helping the body make more SMN protein and maintain SMN protein levels throughout the body with continued use. This reduces the loss of nerve cells and may improve muscle strength and function in a broad range of ages and SMA types.

In infants with SMA, EVRYSDI improves survival, preserves swallowing, improves likelihood of achieving milestones, and reduces the need for hospitalization and ventilator supported breathing. In children (infants to adolescents) and adults, EVRYSDI may maintain or improve motor function over time.

Before you use EVRYSDI

- When you must not use it

Do not take EVRYSDI if:

1. you are allergic to risdiplam or any of the ingredients in EVRYSDI. See the end of this leaflet for a complete list of ingredients in EVRYSDI.
2. the package is torn or shows signs of tampering
3. the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

- Before you start to use it

Before taking EVRYSDI, tell your healthcare provider about all of your medical conditions.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare provider, including your pharmacist, when you get a new medicine.

How to use EVRYSDI

See the detailed Instructions for Use that comes with EVRYSDI for information on how to take or give EVRYSDI oral solution.

Once transferred from the bottle to the oral syringe, take EVRYSDI right away. Do not store the EVRYSDI solution in the syringe. If EVRYSDI is not taken within 5 minutes of when it is drawn up, EVRYSDI should be thrown away from the reusable oral syringe, and a new dose should be prepared.

- Use the oral syringes provided

It is important that you use the oral syringe provided in the pack to measure your or your child's dose of EVRYSDI as they are specially designed to protect medication from light.

Contact your healthcare provider if your oral syringes are lost or damaged, and they will advise you on how to continue to take your medication.

- How much to use

- For infants and children, your healthcare provider will determine the daily dose of EVRYSDI needed based on your child's age and weight. For adults, take 5 mg of EVRYSDI daily.
- Take EVRYSDI exactly as your healthcare provider tells you to take it. Do not change the dose without talking to your healthcare provider.

If you do not swallow the full dose, or vomit after taking a dose of EVRYSDI, do not take an extra dose. Instead, just take the next dose at the usual time the next day.

- When to use it

Take EVRYSDI one time daily with or without a meal about the same time each

day. Drink water afterwards to make sure EVRYSDI has been completely swallowed.

In infants who are breastfed, EVRYSDI can be given before or after breastfeeding.

Do not mix EVRYSDI with formula or milk.

If you are unable to swallow and have a nasogastric (NG-tube) or gastrostomy tube (G-tube), EVRYSDI can be given through the tube.

- How long to use it

Your healthcare provider will tell you how long to take EVRYSDI for. Do not stop treatment with EVRYSDI unless your healthcare provider tells you to.

- If you forget to use it

- If you miss a dose of EVRYSDI:
 - If you remember the missed dose within 6 hours of when you normally take EVRYSDI, then take or give the dose. Continue taking EVRYSDI at your usual time the next day.
 - If you remember the missed dose more than 6 hours after you normally take EVRYSDI, skip the missed dose. Take your next dose at your usual time the next day.

- If you use too much (overdose)

If you take more EVRYSDI than you should, talk to a doctor or go to hospital straight away. Take the medicine pack and this leaflet with you.

While you are using EVRYSDI

- Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was ineffective and change your treatment unnecessarily.

Tell your doctor if you feel your symptoms have worsened after taking EVRYSDI.

- Things you must not do

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Avoid getting EVRYSDI on your skin or in your eyes. If it gets on your skin, wash the area with soap and water. If EVRYSDI gets in your eyes, rinse your eyes with water.

Do not stop taking EVRYSDI or change the dose without first checking with your doctor.

Do not give EVRYSDI to anyone else even if they have the same condition as you.

- Things to be careful of

Pregnancy:

If you are pregnant, or are planning to become pregnant, ask your healthcare provider for advice before taking this medicine. EVRYSDI may harm your unborn baby.

If you are a woman who can become pregnant:

Before you start your treatment with EVRYSDI, your healthcare provider may test you for pregnancy. Because EVRYSDI may harm your unborn baby, you and your healthcare provider will decide if taking EVRYSDI is right for you during this time.

Contraception:

For women

Talk to your healthcare provider about birth control methods that may be right for you. Use birth control while on treatment and for at least 1 month after stopping EVRYSDI.

For men

Use highly effective contraception (e.g. condom) during your treatment with EVRYSDI and continue to use it 4 months after treatment has finished.

Breast-feeding:

If you are breastfeeding or plan to breastfeed. It is not known if EVRYSDI passes into breast milk and may harm your baby. If you plan to breastfeed, discuss with your healthcare provider about the best way to feed your baby while on treatment with EVRYSDI.

Male fertility:

If you are an adult male planning to have children: EVRYSDI may affect a man's ability to have children (fertility). If this is of concern to you, make sure to ask a healthcare provider for advice.

Side effects

The most common side effects of EVRYSDI include:

For later-onset SMA:

- Fever
- Diarrhea
- Rash

For infantile-onset SMA:

- Fever
- Diarrhea
- Rash
- Runny nose, sneezing and sore throat (upper respiratory infection)
- Lung infection (lower respiratory infection)
- Constipation
- Vomiting
- Cough

These are not all of the possible side effects of EVRYSDI.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of EVRYSDI

- Storage

- Keep this medicine out of the sight and reach of children.
- Store the oral solution in the refrigerator at 2°C to 8°C. Do not freeze.
 - If necessary, you or your caregiver may store the oral solution at room temperature (below 40°C [104°F]) for no more than a total combined time

of 5 days.

- Keep the oral solution in the original amber bottle.
- Keep the oral solution bottle in an upright position.
- When transferring the oral solution from the bottle to the oral syringe, use EVRYSDI right away. Do not store the EVRYSDI solution in the syringe.
- Wash the syringes per instructions after use. Do not throw the syringes away.
- The oral solution can be used for 64 days after constitution by your healthcare provider when stored in the refrigerator at 2°C to 8°C (36°F to 46°F). Discard the medicine after the "DISCARD AFTER" date written on the bottle label or discard the medicine if the bottle has been stored at room temperature (below 40°C [104°F]) for more than a total combined time of 5 days. Discard the medicine if the bottle has been stored at above 40°C (104°F).

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

You should receive EVRYSDI from healthcare provider as a liquid for oral administration that can be given by mouth or through a feeding tube. The liquid solution is prepared by your pharmacist. If the medicine in the bottle is a powder, do not use it. Contact your healthcare provider for a replacement.

Each EVRYSDI bottle is filled with 2.0 g of powder containing 60 mg risdiplam.

When constituted to a greenish yellow to yellow, strawberry flavored oral solution by your pharmacist, in total the volume of the solution is 80 mL. Each mL of the constituted oral solution contains 0.75 mg risdiplam.

Each EVRYSDI pack contains 1 bottle, 1 press-in bottle adapter, 2 plastic 1 mL re-

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usable oral syringes, 2 plastic 6 mL re-usable oral syringes and 1 plastic 12 mL re-usable oral syringes.

Ingredients

- **Active ingredient:**
risdiplam
- **Inactive ingredients:**
ascorbic acid,
disodium edetate dihydrate,
isomalt,
mannitol,
polyethylene glycol 6000, sodium benzoate,
strawberry flavor,
sucralose,
tartaric acid.

MAL number(s)

MAL21086002ARZ
MAL25036008ARSZ

Manufacturer

F. Hoffmann-La Roche Ltd, Basel,
Switzerland

or

F. Hoffmann-La Roche Ltd, Kaiseraugst,
Switzerland

Product Registration Holder

Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
47500 Subang Jaya, Selangor, Malaysia.

Date of revision

13/04/2026

MYPIEvrysdi20260413CDS13.0
(English)

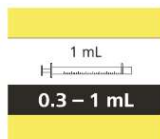
Serial Number

NPRA (R1)24/039

A) Preparing and withdrawing your daily dose

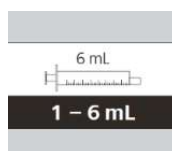
How to select the correct oral syringe to use for your prescribed dose volume of EVRYSDI

If your prescribed daily dose of EVRYSDI is between 0.3 mL and 1 mL, use a 1 mL oral syringe (yellow

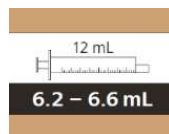


label).

If your prescribed daily dose of EVRYSDI is between 1 mL and 6 mL, use a 6 mL oral syringe (grey label).



If your prescribed daily dose of EVRYSDI is 6.2 mL or higher, use a 12 mL oral syringe (brown label).



Ask your HCP about rounding you or your child's daily dose to the nearest syringe marking.

How to prepare your daily dose of EVRYSDI

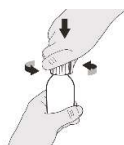


Figure B

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.

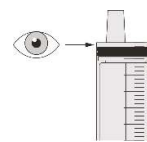


Figure C

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).

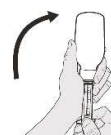


Figure E

Step A4

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

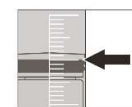


Figure F

Step A5

Slowly pull back on the plunger to withdraw your prescribed daily dose 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 (See Figure F).

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

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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 daily dose 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.

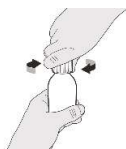


Figure I

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 daily dose of EVRYSDI by mouth, follow the instructions in **“B) How to take a daily dose of EVRYSDI by mouth”**.

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

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

EVRYSDI's oral syringes are specifically designed to be compatible with the ENFit[®] system. If your feeding tube is not ENFit[®] compatible, you may need an ENFit[®] transition connector to connect the EVRYSDI syringe to your G-tube or NG-tube.

B) How to take a daily dose of EVRYSDI by mouth

Sit upright when taking a daily dose 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.

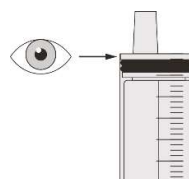


Figure K

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 (See Figure L).

Go to Step E for cleaning of the syringe.

C) How to give a daily dose 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.

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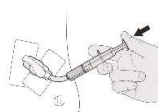


Figure M

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 EVRYSID (See Figure M).

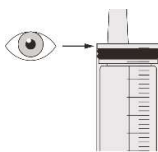


Figure N

Step C2

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

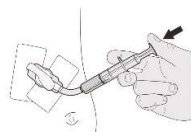


Figure O

Step C3

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

Go to Step E for cleaning of the syringe.

D) How to give a daily dose of EVRYSID through a nasogastric tube

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



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 EVRYSID (See Figure P).

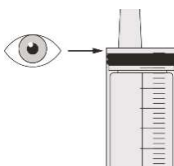


Figure Q

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 EVRYSID (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).

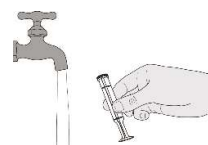


Figure T

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.

EVRYSID (risdiplam)

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