

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Evrysdi® 5 mg tablets

Film-coated tablets

**Active ingredient**
risdiplam 5 mg

For information regarding inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Further information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist. This medicine has been prescribed to treat your illness or your child's illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar to yours.

1. What is this medicine intended for?

Evrysdi is indicated for the treatment of spinal muscular atrophy (SMA) types 1, 2, and 3 in children and adults.

Therapeutic group: medicines for neuromuscular disorders.

SMA is caused by a shortage of a protein called survival motor neuron (SMN) protein. Lack of SMN protein can cause you or your child to lose motor neurons, which are nerve cells that control muscles. This leads to muscle weakness.

How Evrysdi works:

Risdiplam, the active ingredient in Evrysdi, helps the body produce more SMN proteins. This means fewer motor neurons are lost, which may improve how well muscles work in people with SMA.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient (risdiplam) or to any of the other ingredients in this medicine (see section 6).
- If you are not sure, talk to your doctor or pharmacist before using Evrysdi.

Special warnings regarding use of the medicine

- Consult your doctor or pharmacist before you take Evrysdi.
- Treatment with Evrysdi may harm your unborn baby or affect male fertility. See the section '**Pregnancy, breastfeeding, and fertility**' for more information.

Children and adolescents

Evrysdi Tablets are not intended for children under the age of two and children below 20 kg.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. Particularly if you are taking or have taken:

- metformin – a medicine used to treat type II diabetes
- other medicines for the treatment of SMA

Using this medicine and food

Evrysdi may be taken with or without food.

Pregnancy, breastfeeding, and fertility**Pregnancy**

- There is no information regarding the use of Evrysdi in pregnant women.
- Before you start treatment with Evrysdi, your doctor will tell you to perform a pregnancy test because Evrysdi may harm your unborn baby.
- Do not take Evrysdi if you are pregnant.

- Do not become pregnant:
 - during your treatment with Evrysdi
 - and for one month after your last dose of Evrysdi

- If you do become pregnant during your treatment, tell your doctor straight away.

You and your doctor will decide what is best for you and your unborn baby.

ContraceptionFor women

You must use a highly effective method of birth control:

- during your treatment with Evrysdi
- for one month after your last dose of Evrysdi

Talk to your doctor about highly effective methods of birth control that you and your partner should use.

For men

If your female partner is of childbearing potential, you need to avoid pregnancy.

Use an especially effective contraceptive:

- during your treatment with Evrysdi
- and for 4 months after your last dose of Evrysdi.

Talk to your doctor about highly effective methods of birth control that you and your partner should use.

Breastfeeding

It is not known whether Evrysdi passes into breast milk. As the risk of harm to a nursing baby is not known, breastfeeding is not recommended while taking this medicine.

Discuss with your doctor if you should stop breastfeeding or if you should stop taking Evrysdi.

Male fertility

Evrysdi may reduce male fertility while on treatment and for up to 4 months after your last dose.

- If you are planning to have a child, ask your doctor for advice.
- Do not donate sperm during your treatment and for 4 months after your last dose of Evrysdi.

Driving and using machines

Evrysdi has no or negligible effect on the ability to drive and operate machines.

Important information about some of this medicine's ingredients

This medicine contains less than 1 mmol (23 mg) sodium per tablet, meaning it is considered 'sodium-free'.

3. How should you use the medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

You will get blister packs of Evrysdi as film-coated tablets, referred to as a 'tablet' in this leaflet. This medicine is also available as an oral solution. Your doctor will help you choose the best option for you.

Dosage

Only your doctor will determine your dose and how you should take this medicine.

If you are taking Evrysdi tablets, the recommended dosage is usually 5 mg (one tablet) once daily.

You must take your daily dose as instructed by your doctor. **Do not exceed the recommended dose.**

Read the 'Instructions for Use of This Medicine' at the end of this leaflet. Follow the instructions carefully. They explain exactly how to prepare and take Evrysdi.

Take Evrysdi:

- Once a day, at around the same time – this will help you remember when to take your medicine.
- With or without food.

There are two ways your doctor may tell you to take Evrysdi tablets:

- Take the tablet by mouth. Swallow the tablet whole with some water.
 - Do not cut, crush or chew the tablets.

Or

- Take the tablet by mouth after mixing it in a small amount of room temperature water.
 - Do not mix Evrysdi with any liquids other than water.
 - Take Evrysdi straight away after mixing with water. If you do not take it within 10 minutes of adding water, throw the mixture away and make a new dose.
 - Do not expose the tablet mixture prepared from the Evrysdi tablet to sunlight.
 - Do not get Evrysdi tablet mixture on your skin or in your eyes. If Evrysdi gets on your skin, wash the area with soap and water. If Evrysdi comes into contact with your eyes, rinse your eyes with water.
 - Do not administer the tablet mixture via a feeding tube

Adhere to the treatment as recommended by your doctor. Even if your health improves, **do not stop treatment with Evrysdi without consulting your doctor.**

If you have taken an overdose, or if a child has accidentally swallowed the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine or vomit after a dose

If you forget to take a dose:

- If 6 hours or less have passed from the time you normally take Evrysdi, take the missed dose as soon as possible.
- If more than 6 hours have passed since the time you normally take Evrysdi, skip the missed dose and then take your next dose at the usual time the next day. **Do not** take a double dose to make up for a forgotten dose.

If you vomit after taking a dose of Evrysdi:

- **do not** take an extra dose. Take the next dose at the usual time the next day.

If you spill the Evrysdi tablet mixture, dry the area with a dry paper towel and then clean the area with soap and water. Throw away the paper towel in the waste and wash your hands well with soap and water.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Evrysdi may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects (may affect more than one in ten users):

- diarrhoea
- rash
- headache
- fever

Common side effects (may affect up to one in ten users):

- nausea
- mouth sores
- bladder infection
- joint pain

Side effect of unknown frequency:

- inflammation of small blood vessels mainly affecting the skin (cutaneous vasculitis).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Storage conditions:

Do not store above 30°C. Store the medicine in the original package in order to protect from moisture.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

6. Further information

In addition to the active ingredient risdiplam, this medicine also contains:

microcrystalline cellulose, mannitol, crospovidone, sodium stearyl fumarate, tartaric acid, silica colloidal anhydrous, strawberry flavour, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, yellow iron oxide

What the medicine looks like and contents of the pack:

- Evrysdi tablets are pale yellow film-coated tablets, round and curved, with EVR debossed on one side.
- A pack of Evrysdi contains 28 film-coated tablets in 4 aluminium blisters containing 7 tablets each.

Registration holder's name and address: Roche Pharmaceuticals (Israel) Ltd., 6 Hacharash, P.O.B 6391, Hod Hasharon 4524079.

www.roche.co.il

Manufacturer's name and address: Hoffmann-La Roche Ltd., Basel, Switzerland.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 180-15-38450-99.

Approved in September 2025.

Evrysdi tablets IFU ver 1**Instructions for Use of this Medicine****Evrysdi 5 mg film-coated tablets**

risdiplam

Before you start

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

Evrysdi film-coated tablets can be swallowed whole or mixed with a small amount of room temperature water and taken by mouth.

Do not give Evrysdi film-coated tablets with a feeding tube.

Important information about Evrysdi

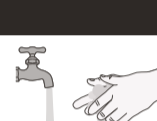
- Your pharmacist, doctor or nurse will show you how to prepare and take Evrysdi tablets. Always take Evrysdi tablets exactly as your doctor instructed.
- Do not take or give this medicine until you have received an explanation of how to properly give and take Evrysdi.
- Wash your hands before and after preparing or taking Evrysdi.
- Check the expiry date and check the medicine before taking it. Do not use if expired or damaged.
- Do not get the Evrysdi tablet mixture on your skin or in your eyes. If the Evrysdi comes into contact with your skin, wash the area with soap and water. If Evrysdi comes into contact with your eyes, rinse your eyes with water.
- Do not expose the tablet mixture prepared to sunlight.
- If you spill 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 waste and wash your hands well with soap and water.

How to take Evrysdi tablets

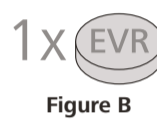
- If you are taking Evrysdi tablets, the daily dose is 1 tablet a day.
- Take the tablet whole with water or as a liquid by mixing 1 tablet in at least 1 teaspoon (5 ml) of room temperature water.
- **Do not** chew, cut, or crush the tablet.
- **Do not** mix Evrysdi with any liquids other than water.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

Get ready to take Evrysdi

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: Taking the Evrysdi tablet whole****Step A1**

Swallow the tablet whole with some water.

- **Do not** chew, cut, or crush the tablet.
- **Do not** mix Evrysdi with any liquids other than water.

Step A2

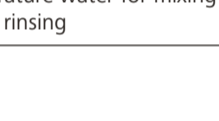
Wash your hands with soap and water.

Option B: Taking Evrysdi mixed with water**What is needed to mix Evrysdi with water:**

- 1 Evrysdi tablet
- a small, clean cup
- at least 1 teaspoon (5 ml) of room temperature water for mixing
- at least 1 tablespoon (15 ml) of water for rinsing

Step B1
Put at least 1 teaspoon (5 ml) of water in a cup – and add 1 tablet

- **Do not** use any liquids other than water
- Keep the mixture out of sunlight

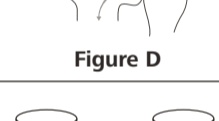
**Figure C**

Step B2
Gently swirl the cup until it is fully mixed - this can take up to 3 minutes (**Figure C**)

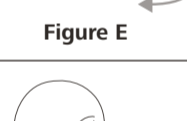
Step B3
Drink immediately within 10 minutes of adding water to the tablet (**Figure D**)

**Figure D**

Step B4
Refill the cup with at least 1 tablespoon (15 ml) of water and swirl to get any medicine left in the cup (**Figure E**)

**Figure E**

Step B5
Drink immediately (**Figure F**)

**Figure F**

Step 6B
Wash your hands with soap and water

Storing Evrysdi

- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- Keep this medicine out of the reach and sight of children.