

Evrysdi_PL_Ver 2.0
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<b>Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986</b>
This medicine is dispensed with a doctor's prescription only

## Evrysdi

### 0.75 mg/mL

Powder for oral solution

**Composition:**

Each bottle contains:

risdiplam 60 mg

Every 1 mL of oral solution contains 0.75 mg risdiplam.

\*For information regarding inactive ingredients and allergens 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 patients 2 months of age and older.

**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 substance in Evrysdi, helps the body produce more SMN protein. This means fewer motor neurons are lost, which may improve how well muscles work in people with SMA.

#### 2. Before using this medicine

<b>Do not use this medicine if:</b> <ul style="list-style-type: none"><li>you or your child are allergic to risdiplam or any of the other ingredients in this medicine (listed in section 6).</li></ul> <p>If you are not sure, talk to your doctor or pharmacist before using Evrysdi.</p>
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**Special warnings regarding use of the medicine**

- Consult your doctor or pharmacist before you or your child take Evrysdi.

**Before taking Evrysdi, tell your doctor if:**

- you are pregnant or planning to become pregnant or if you are a man planning to have a child. Treatment with Evrysdi may harm your unborn baby or affect male fertility. See the section ‘**Pregnancy, breastfeeding, and fertility**’ for more information.
- you or your child have an intolerance (sensitivity) to certain sugars.
- you have ever been given gene therapy for SMN1.

**Children and adolescents**

This medicine is not intended for infants under 2 months of age.

**Interactions with other medicines**

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

Take Evrysdi after a meal.

**Pregnancy, breastfeeding, and fertility**

**Pregnancy**

- Do not take Evrysdi if you are pregnant. Taking this medicine while you are pregnant could harm your unborn baby.
- Before you start treatment with Evrysdi, your doctor will tell you to perform a pregnancy test because Evrysdi may harm your unborn baby.
- If you do become pregnant during your treatment with Evrysdi, tell your doctor straight away.

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

**Contraception**

For women

Do not become pregnant:

- during your treatment with Evrysdi
- for one month after you stop taking Evrysdi.

Talk to your doctor about reliable methods of birth control that you and your partner should use during treatment with Evrysdi and for one month after you stop treatment.

For men

If your female partner is of childbearing potential, you need to avoid pregnancy. Use contraceptives during your treatment with Evrysdi and continue for 4 months after you stop treatment.

**Breastfeeding**

Do not breastfeed while taking this medicine. This is because it is not known if Evrysdi can pass into breast milk and may, therefore, harm your baby.

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

**Male fertility**

Based on findings in animals, 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 is unlikely to affect your ability to drive and use machines, because Evrysdi has no or negligible effect on ability to drive and operate machines.

**Important information about some of this medicine’s ingredients**

- Evrysdi contains a small amount of sodium (salt) - there is less than 1 mmol (23 mg) sodium in the highest daily dose of 5 mg Evrysdi (6.6 mL of 0.75 mg/mL oral solution). This means that this medicine is essentially ‘sodium-free’ and can be used by people on a sodium-restricted diet.
- Evrysdi contains 0.375 mg of sodium benzoate per mL. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Evrysdi contains 2.97 mg of isomalt per mL. If you have been told by your doctor that you or your child have an intolerance to some sugars, consult your doctor before taking this medicine.

#### 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 should receive Evrysdi from the pharmacy as a liquid in a bottle (oral solution). **Do not use** if the medicine in the bottle is a powder, and contact your pharmacy. The pack contains instructions for constitution which are intended for the pharmacy, and instructions for use which are intended for you. Read the instructions for use carefully.

Dosage

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

The recommended dosage is usually:

<b>Age and body weight</b>	<b>Recommended daily dose</b>
Age 2 months to 2 years	0.20 mg/kg
Age 2 years and up (under 20 kg)	0.25 mg/kg
Age 2 years and up (20 kg and up)	5 mg

#### Do not exceed the recommended dose.

Taking this medicine

- You should receive Evrysdi from the pharmacy as an oral solution.
- You should take Evrysdi once daily after a meal (or after breastfeeding if this is a breastfed baby) at around the same time each day. Drink water after taking the medicine to make sure the whole dose has been swallowed.
- Do not mix the medicine with formula milk or milk.
- Take or give Evrysdi immediately after it is withdrawn from the bottle into the oral syringe. If it is not taken within 5 minutes of drawing up into the syringe, discard the medicine from the oral syringe, and withdraw a new dose from the bottle.
- If you or your child are unable to swallow and you or your child have a nasogastric tube (NG tube) or gastrostomy tube, Evrysdi can be given through the tube. Flush the tube after giving Evrysdi.
- If Evrysdi gets on your own or your child’s skin, wash the area with soap and water.

For information about how to take your dose using the re-usable oral syringe included in the pack **read the Instructions for Use carefully.** You or your child can take the medicine by mouth or through a gastrostomy or nasogastric tube.

**If you or your child has 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 or your child forget to take Evrysdi or vomit after a dose**

- If you remember the missed dose within 6 hours of the time you normally take Evrysdi, take the missed dose as soon as possible. Take the next dose at the usual time the next day.
- If you remember the missed dose more than 6 hours after 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 or your child vomit after taking a dose of Evrysdi or if the dose is not fully swallowed, **do not** take an extra dose. Take the next dose at the usual time the next day.

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

**If you spill Evrysdi,** 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 (affect more than 1 in 10 users):

- diarrhoea
- rash
- headache
- fever

Common side effects (affect 1-10 in 100 users):

- nausea
- mouth sores
- bladder infection
- joint pain

The following side effect has been reported since the marketing of Evrysdi, but the frequency for it is not known:

- 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](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://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 a doctor.

**Storage conditions before constitution (dry powder):**

Do not store above 25°C. Store the medicine in the original bottle in order to protect from light.

You should receive Evrysdi from the pharmacy as a liquid in a bottle. The oral solution is prepared by your pharmacist. If the medicine in the bottle is in powder form, do not take Evrysdi and contact your pharmacist.

The oral solution is stable for 64 days after the pharmacist prepares it. The pharmacist will write Discard after date on the medicine package. **Do not use the medicine after the Discard after date noted by the pharmacist.**

**Storage conditions after constitution (oral solution):**

- Store the solution in a refrigerator at 2°C-8°C. Do not freeze.
- Keep the solution in the original bottle to protect from light.
- Keep the bottle upright, with the cap tightly closed.
- Once you have withdrawn the medicine from the bottle into the syringe, use Evrysdi straight away. Do not store the solution in the syringe.

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: mannitol, isomalt, strawberry flavour, tartaric acid, sodium benzoate, macrogol/ polyethylene glycol 6000, sucralose, ascorbic acid, disodium edetate dihydrate.

What the medicine looks like and contents of the pack

- Each pack contains one bottle, one press-in bottle adapter, two 6-mL and two 12-mL re-usable amber oral syringes with markings to help you withdraw the right dose.
- Evrysdi is a powder for preparing an oral solution, and it is dispensed as an oral solution after preparation by the pharmacist. The solution is greenish yellow to yellow.

**Registration holder’s name and address:** Roche Pharmaceuticals (Israel) Ltd., 6 Hacharash Street, POB 6391, Hod Hasharon 4524079.

[www.roche.co.il](http://www.roche.co.il)

**Manufacturer’s name and address:** Hoffmann-La Roche Ltd., CH-4070, Basel, Switzerland.

**Revised in January 2022 according to MOH guidelines.**

**Registration number of the medicine in the Ministry of Health’s National Drug Registry: 167-71-36630-99.**