Evrysdi®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I taking Evrysdi?

Evrysdi contains the active ingredient risdiplam. Evrysdi is used to treat spinal muscular atrophy (SMA). For more information, see Section 1. Why am I taking Evrysdi? in the full CMI.

2. What should I know before I take Evrysdi?

Do not take if you have ever had an allergic reaction to risdiplam or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, or are breastfeeding. If you are female, your doctor may do a pregnancy test to confirm you are not pregnant.
If you are male and planning to donate sperm or have children, talk to your doctor. For more information, see Section 2. What should I know before I take Evrysdi? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Evrysdi?

- Take Evrysdi once a day, at approximately the same time each day, with or without food.
- The recommended dose in adults and adolescents is 5 mg a day. Your doctor will decide the dose for infants and children based on their age and body weight.

More information can be found in Section 4. How do I take Evrysdi? in the full CMI and in the Instructions for use leaflet provided in the pack.

5. What should I know while taking Evrysdi?

Things you should do	• Men and women should use contraception during treatment and for at least 1 month (women) or for at least 4 months (men) after stopping treatment. • If you do become pregnant during treatment with Evrysdi, tell your doctor straight away.
Things you should not do	• Do not stop treatment with Evrysdi unless your doctor tells you to. • Avoid getting Evrysdi on your skin. If Evrysdi gets on your skin, wash the area with soap and water.
Driving or using machines	• Evrysdi is unlikely to affect your ability to drive and use machines.
Looking after your medicine	• **Evrysdi solution**: Store the oral solution at 2°C to 8°C (refrigerate, do not freeze) in the original bottle. Discard the medicine after the expiry date printed on the bottle label or after 64 days (refer to the "Discard contents after" date written on the bottle label). 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 bottle closed tightly and in an upright position. Once transferred to the oral syringe, use right away. Do not store the solution in the syringe. • **Evrysdi tablet**: Store in the original package in order to protect from moisture. Store below 30°C

For more information, see Section 5. What should I know while taking Evrysdi? in the full CMI.

6. Are there any side effects?

Serious side effects include difficulty breathing, rapid breathing or shortness of breath; increased heart rate; blue lips, fingertips or skin; watery or bloody diarrhea; bleeding into the skin; skin hives or skin ulcers; joint dislocation; bloody urine and curved spine. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Evrysdi®

Active ingredient: *risdiplam*
Evrysdi® (risdiplam) 0.75 mg/ml powder for oral solution
Evrysdi® (risdiplam) 5 mg film-coated tablet

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Evrysdi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Evrysdi.**

Where to find information in this leaflet:

1. Why am I taking Evrysdi?
2. What should I know before I take Evrysdi?
3. What if I am taking other medicines?
4. How do I take Evrysdi?
5. What should I know while taking Evrysdi?
6. Are there any side effects?
7. Product details

1. Why am I taking Evrysdi?

Evrysdi contains the active ingredient risdiplam. Risdiplam is a selective survival of motor neuron 2 (SMN2) gene splicing modifier.

Evrysdi is used to treat spinal muscular atrophy (SMA).

SMA is a genetic condition people can be born with, that is caused by a shortage of a protein called "survival of motor neuron" (SMN) in the body. The SMN protein is needed for nerves to function properly. Not having enough SMN protein results in the loss of motor neurons, leading to muscle weakness and muscle wasting. Basic activities such as head and neck control, sitting, crawling and walking may be affected. The muscles used for breathing and swallowing may also be affected.

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 motor milestones, and reduces the need for hospitalisation and ventilator supported breathing. In children (infants to adolescents) and adults, Evrysdi may maintain or improve motor function over time.

2. What should I know before I take Evrysdi?

Warnings

Do not take Evrysdi if:

- you are allergic to risdiplam, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have any other medical conditions
- have a kidney or liver disorder
- take any medicines for any other condition
- are female and pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed (see Pregnancy)
- are male and planning to donate sperm or have children (see Male fertility)
- have any issues with the structure of your eye
- have been diagnosed with Type 0 or IV SMA
- are older than 60 years

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Contraception

For women: You should use highly effective contraception **during treatment** and for at least **1 month after you stop** treatment with Evrysdi.

For men: If your female partner is of childbearing potential, you and your partner should both use highly effective contraception **during treatment** and for at least **4 months after you stop taking Evrysdi**.

Talk to your healthcare provider about reliable methods of contraception that should be used.

Pregnancy

Evrysdi could harm your unborn baby. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will consider the benefit of you taking Evrysdi against the risk to your baby.

Before you start treatment with Evrysdi, your doctor may do a pregnancy test to confirm you are not pregnant.

If you do become pregnant during treatment with Evrysdi, tell your healthcare provider doctor straight away. You and your doctor will decide what is best for you and your unborn baby.

Breastfeeding

Do not breastfeed while taking this medicine. This is because Evrysdi may pass into breast milk and may harm your baby.

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

Male fertility

Evrysdi may affect fertility in men.

Do not donate sperm during your treatment and for at least 4 months after you stop taking Evrysdi.

For your family planning, ask your doctor for advice.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these could affect Evrysdi.

Evrysdi may increase the effect of:

- metformin
- fexofenadine

Evrysdi may affect your eye. Tell your doctor if you are taking other medicines that affect the eye while taking Evrysdi.

4. How do I take Evrysdi?

Evrysdi is a liquid or a film-coated tablet, and is referred to as a 'solution' or 'tablet' in this leaflet. Your doctor will help you choose the right one for you.

How much to take

Evrysdi solution

- **Adolescents and adults:** The daily dose of Evrysdi is 5 mg (6.6 mL of the 750 microgram/mL oral solution).
- **Infants and children:** Your doctor will determine the daily dose of Evrysdi based on your child's age and weight.

Evrysdi tablet

- The daily dose is 5 mg (one tablet).
- Available for patients aged 2 years or older weighing 20 kg or more

You must take your daily dose as instructed by your doctor. Do not change the dose without speaking to your doctor.

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 take Evrysdi

- Take Evrysdi once daily at approximately the same time each day. This will help you remember when to take your medicine.
- You can take Evrysdi with or without food.
- If your baby is being breastfed, you can give your baby Evrysdi after breastfeeding.

How to take Evrysdi

Always take this medicine exactly as your healthcare provider has told you. Check with your healthcare provider if you are not sure.

Read carefully and follow the **"Instructions for use" leaflet** enclosed in the pack on how to take or give Evrysdi solution or Evrysdi tablet.

Evrysdi solution

You should receive Evrysdi from your healthcare provider as a liquid for oral administration that can be given by mouth or through a feeding tube. Do not mix Evrysdi with formula or milk.

Use only oral syringes provided.

It is important that you only 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 the medicine from light.

If your oral syringes are lost or damaged, contact your healthcare provider and they will advise you on how to continue to take your medicine.

Evrysdi tablet

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

Swallow each tablet whole by mouth with some water.

- Do not cut, crush or chew the tablets.

Or

Disperse the tablet in water and take by mouth or via a feeding tube.

- Put at least 5 mL (1 teaspoon) of non-chlorinated drinking water (e.g bottled water) in a cup with 1 Evrysdi tablet
- Do not mix Evrysdi with any liquids other than non-chlorinated drinking water (e.g bottled water)
- Gently swirl the cup as needed until the tablet and non-chlorinated drinking water (e.g bottled water) are fully mixed (though some particles may remain). This may take up to 3 minutes

Taking Evrysdi tablet by mouth:

- Take Evrysdi tablet mixture straight away after mixing with non-chlorinated drinking water (e.g bottled water). If you do not take it within 10 minutes of mixing with non-chlorinated drinking water (e.g bottled water), throw the mixture away and make a new dose
- To make sure there is no medicine left, refill the cup with at least 15 mL (1 tablespoon) of non-chlorinated drinking water (e.g bottled water) and swirl and drink the tablet mixture immediately
- Do not expose the tablet mixture to sunlight.

Administering Evrysdi tablet via feeding tube:

- Administer Evrysdi tablet mixture straight away after mixing with non-chlorinated drinking water (e.g bottled water). If you do not take it within 10 minutes of mixing with non-chlorinated drinking water (e.g bottled water), throw the mixture away and make a new dose
- Place the syringe top into the cup right away and pull up the plunger to draw the mixture
- Place the syringe tip into the feeding tube and press the plunger down to give the full dose of Evrysdi
- To make sure there is no medicine left, refill the cup with at least 15 mL (1 tablespoon) of non-chlorinated drinking water (e.g bottled water) and swirl. Place the syringe into the cup, redraw the mixture and flush the feeding tube with the mixture.

If you forget to take Evrysdi

Evrysdi should be taken regularly at the same time each day. If you miss your dose at the usual time:

- If it is within 6 hours of when you normally take Evrysdi, take the missed dose as soon as you remember.
- If it is over 6 hours from when you normally take Evrysdi, skip the missed dose and then take your next dose at the usual time.

Do not take a double dose to make up for the dose you missed.

If you vomit after a dose

If you vomit after taking Evrysdi, do not take an extra dose. Instead, take the next dose at the usual time the next day.

If you spill Evrysdi, or get it on your skin or in your eye

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 gets in your eyes, rinse your eyes with water.

If you spill 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 rubbish and wash your hands well with soap and water.

If you take too much Evrysdi

If you think that you have taken too much Evrysdi, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Take the medicine pack and this leaflet with you.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Evrysdi?

Things you should do

- Use contraception during treatment (men and women) and for at least 1 month after stopping treatment (women), or for at least 4 months after stopping treatment (men) (see Contraception).
- If you do become pregnant during treatment with Evrysdi, tell your healthcare provider doctor straight away (see Pregnancy).
- Inform any other doctor or health professional you visit that you are taking Evrysdi.

Things you should not do

- Do not stop treatment with Evrysdi unless your doctor tells you to.
- Avoid getting Evrysdi on your skin. If Evrysdi gets on your skin, wash the area with soap and water.

Driving or using machines

Evrysdi is unlikely to affect your ability to drive and use machines.

Looking after your medicine

Evrysdi solution

- 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, take Evrysdi right away. Do not store the Evrysdi solution in the syringe.

Wash the syringes as described in the **"Instructions for use" leaflet**. Do not throw them away.

Evrysdi film-coated tablets

- Store Evrysdi below 30°C

- Keep in the original package to protect from moisture.

When to discard your medicine (as relevant)

Evrysdi oral solution can be taken for up to 64 days after reconstitution by your pharmacist when stored in the refrigerator at 2℃ to 8℃. Your pharmacist will write the "Discard contents after" date on the bottle label.

Discard the medicine:

- after the expiry date printed on the bottle label or after the “Discard contents after” date written on the bottle label,
- or if the medicine has been stored at room temperature (below 40℃) for more than a total combined time of 5 days,
- or if the medicine has been stored at above 40℃.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to a pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects include

Less serious side effects	What to do
Stomach related: • constipation or • diarrhea • nausea • vomiting • pain in the upper region of the stomach • heartburn, difficulty swallowing, a chronic cough **Skin related** • rash • ulcers in the mouth and the inside of the lip and cheek • eczema **Airway related** • Cough • Runny or stuffy nose **General** • fever • teething • headache	**Speak to your doctor if you have any of these side effects and they worry you.**
Muscle and joint related • swelling and pain in the joints **Infections** • urinary tract infection, symptoms include strong and frequent urge to urinate, cloudy, bloody or strong-smelling urine, pain or a burning sensation when urinating • infection of the airways, symptoms include runny nose, stuffy nose, cough, sore throat, fever • ear infection, symptoms include pain in the ear, fever, loss of balance, difficulty hearing • infection and inflammation of the digestive system (gastroenteritis), symptoms include watery and possibly bloody diarrhea, stomach cramps, nausea, vomiting, fever	

Serious side effects include

Serious side effects	What to do
Lung related • difficulty breathing, rapid breathing or shortness of breath, tightness in the chest, shallow breaths or flaring of the nostrils, wheezing, tiredness or loss of consciousness • your skin, fingernails or lips look blue or pale • infection of the airways, symptoms include fever, chills, shortness of breath, cough, phlegm and occasionally blood in the phlegm **Skin related** • cutaneous vasculitis, inflammation of the blood vessels of the skin, causing them to be narrowed or blocked. Symptoms include areas if flat and red skin, raised skin, bleeding into the skin causing small red or reddish-blue to purple spots or net-like patterns on the skin, skin hives ((raised red patches of skin that are often	**Call your doctor straight away, or if you have symptoms of palpitations, shortness of breath, dizziness, chest pain, lightheadedness and fainting, please go to your nearest emergency department.**

very itchy) or skin ulcers (round open sores in the skin) **Kidney and bladder related** • bloody urine **Bone, muscle and joint related** • dislocation of a joint • sideways curvature of the spine **Metabolism** • dehydration **Related to the reproductive system** • undescended testicle or testis **Heart related** • increased heart rate	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Evrysdi solution contains

Evrysdi solution contains a small amount of sodium. Patients on a sodium restricted diet should talk to their doctor about whether they can take Evrysdi.

Active ingredient (main ingredient)	Risdiplam
Other ingredients (inactive ingredients)	Mannitol Isomalt Strawberry flavour Tartaric acid Sodium benzoate Macrogol 6000 Sucralose Ascorbic acid Disodium edetate

Do not take this medicine if you are allergic to any of these ingredients.

When prepared by your healthcare provider, the volume of the solution is 80 mL. Each mL of the reconstituted oral solution contains 750 micrograms of risdiplam.

Each Evrysdi solution pack contains 1 bottle of the medicine and press-in bottle adapter, 2 plastic 1mL re-usable oral syringes, 2 plastic 6 mL re-usable oral syringes and 1 plastic 12 mL re-usable oral syringe.

What Evrysdi tablet contains

Evrysdi tablet contains a small amount of sodium. Patients on a sodium restricted diet should talk to their doctor about whether they can take Evrysdi.

Active ingredient (main ingredient)	Risdiplam
Other ingredients (inactive ingredients)	Tartaric acid Mannitol Microcrystalline cellulose Colloidal anhydrous silica Crospovidone Strawberry flavour PHD-180152 Sodium stearyl fumarate Polyvinyl alcohol Titanium dioxide Macrogol 3350 Purified talc Iron oxide yellow (E172, C.I 77492)

Do not take this medicine if you are allergic to any of these ingredients.

Each Evrysdi tablet pack contains 28 film-coated tablets. There are 4 blister strips with 7 tablets per strip.

What Evrysdi looks like

Evrysdi powder for oral solution (AUST R 340350):

You should receive Evrysdi from your healthcare provider as a greenish yellow to yellow, strawberry flavoured oral solution. The liquid solution must be prepared by your healthcare provider. **If the medicine in the bottle is a powder, do not take it.** Contact your healthcare provider for a replacement.

Evrysdi film-coated tablets (AUST R 453545):

Evrysdi tablets are pale yellow film-coated tablets, round and curved, with EVR debossed on one side.

Who distributes Evrysdi

Evrysdi is distributed in Australia by:

Roche Products Pty Ltd
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

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