

Evrysdi®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using 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 using 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 using Evrysdi?](#) in the full CMI.

2. What should I know before I use Evrysdi?

Do not use 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 use 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 use Evrysdi?

- Take Evrysdi orally (by mouth or through a feeding tube) once a day, at approximately the same time each day, after a meal, using only the oral syringes provided in the pack.
- The recommended dose in adults and adolescents is 5 mg (6.6 mL) 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 use Evrysdi?](#) in the full CMI and in the "Instructions for use" leaflet provided in the pack.

5. What should I know while using Evrysdi?

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|---------------------------------|--|
| Things you should do | <ul style="list-style-type: none">● Use contraception during treatment (men and women) and for 1 month after stopping treatment (women), or for 4 months after stopping treatment (men) (see Contraception in the full CMI).● If you do become pregnant during treatment with Evrysdi, tell your doctor straight away (see Pregnancy in the full CMI).● Inform any other doctor or health professional you visit that you are using Evrysdi. |
| Things you should not do | <ul style="list-style-type: none">● 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 | <ul style="list-style-type: none"> • Evrysdi is unlikely to affect your ability to drive and use machines. |
| Looking after your medicine | <ul style="list-style-type: none"> • Store the oral solution at 2°C to 8°C (refrigerate, do not freeze) in the original bottle. Discard any unused portion after 64 days (refer to "Discard contents after" date on the bottle). • 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. |

For more information, see Section [5. What should I know while using Evrysdi?](#) in the full CMI.

6. Are there any side effects?

Serious side effects include pneumonia and respiratory failure (insufficient oxygen or too much carbon dioxide in the blood).

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*

Consumer Medicine Information (CMI)

This leaflet provides important information about using 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 using Evrysdi.**

Where to find information in this leaflet:

- [1. Why am I using Evrysdi?](#)
- [2. What should I know before I use Evrysdi?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Evrysdi?](#)
- [5. What should I know while using Evrysdi?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using 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) in patients 2 months and older.

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 (toddlers to adolescents) and adults, Evrysdi may maintain or improve motor function over time.

2. What should I know before I use 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 use 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 or if your baby is younger than 2 months

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 **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 **4 months after treatment** with Evrysdi has finished.

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 4 months after your last dose of 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 use Evrysdi?

Evrysdi is a liquid, and is referred to as a 'solution' or 'medicine' in this leaflet.

How much to take

- **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.

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 should take Evrysdi after a meal.

- 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.

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.

If you forget to take Evrysdi

Evrysdi should be used 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 use 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 using Evrysdi?

Things you should do

- Use contraception during treatment (men and women) and for 1 month after stopping treatment (women),

or for 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 using 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

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

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

When to discard your medicine (as relevant)

Dispose of the medicine after the “Discard contents after” date written on the bottle label. Evrysdi oral solution can be used for 64 days after reconstitution by your healthcare provider.

Getting rid of any unwanted medicine

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

Do not use 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
- diarrhea
- nausea
- vomiting
- pain in the upper region of the stomach

Skin related

- rash
- ulcers in the mouth and the inside of the lip and cheek

General

- fever
- teething
- headache

Lung related

- cough

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-

Speak to your doctor if you have any of these side effects and they worry you.

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| <p>smelling urine, pain or a burning sensation when urinating</p> <ul style="list-style-type: none"> ● infection of the upper airways, symptoms include runny nose, stuffy nose, cough, sore throat ● ear infection, symptoms include pain in the ear, fever, loss of balance, difficulty hearing ● viral infections, symptoms include sore throat, runny or stuffy nose, cough, mild body aches, low-grade fever, sneezing | |
|--|--|

Serious side effects include

| Serious side effects | What to do |
|--|--|
| <p>Lung related</p> <ul style="list-style-type: none"> ● pneumonia, symptoms include fever, chills, shortness of breath, cough, phlegm and occasionally blood ● respiratory failure, a condition in which there | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

is insufficient oxygen or too much carbon dioxide in the blood. Symptoms include difficulty breathing or shortness of breath, wheezing, rapid breathing, your skin, fingernails or lips look blue, tiredness or loss of consciousness

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 contains

| | |
|---|--|
| 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 reconstituted 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 pack contains 1 bottle of the medicine and press-in bottle adapter, 2 plastic 6 mL re-usable oral syringes and 2 plastic 12 mL re-usable oral syringes.

What Evrysdi looks like

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 use it.** Contact your healthcare provider for a replacement.

Evrysdi is a powder for oral solution (AUST R 340350).

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.

This leaflet was prepared in June 2021.