

▼ 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®
risdiplam

Consumer Medicine Information

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.