Evrysdi is now approved for more people with spinal muscular atrophy (SMA)

Evrysdi in infants treated before symptoms appeared

RAINBOWFISH is an ongoing, open-label study that measures the safety and effectiveness of Evrysdi in infants 16 to 40 days of age (at first dose). At the time initial results were collected:

- 18 infants had enrolled in the study
- There were not enough study participants to evaluate the main effectiveness measurement (sitting for at least 5 seconds)*
- 6 infants received Evrysdi for at least 12 months and were included in the measurement of effectiveness
  - These infants had either 2 or 3 copies of the *SMN2* gene

After 12 months of treatment with Evrysdi

100% (6/6) could sit†

50% (3/6) could walk†

67% (4/6) could stand†

100% (6/6) were alive and able to breathe without permanent support‡

* Measured at 12 months by Item 22 of the Bayley Scales of Infant and Toddler Development–Third Edition (BSID-III) among at least 5 infants with 2 copies of the *SMN2* gene and compound muscle action potential (CMAP) amplitude ≥1.5 mV at the start of the study.

† Measured with the Hammersmith Infant Neurological Examination Module 2 (HINE-2), which assesses developmental milestones for infants, including head control, sitting, voluntary grasp, ability to kick, rolling, crawling, standing, and walking.

‡ Defined as having a tracheostomy or more than 21 days of either noninvasive ventilation support (16 or more hours a day) or being intubated to help with breathing, in the absence of an acute reversible event.

What is Evrysdi?

Evrysdi is a prescription medicine used to treat spinal muscular atrophy (SMA) in children and adults.

Important Safety Information

Before taking Evrysdi, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant, as Evrysdi may harm your unborn baby. Ask your healthcare provider for advice before taking this medicine
- are a woman who can become pregnant:
  - Before you start your treatment with Evrysdi, your healthcare provider may test you for pregnancy
  - Talk to your healthcare provider about birth control methods that may be right for you. Use birth control while on treatment and for at least 1 month after stopping Evrysdi
- are an adult male. Evrysdi may affect a man's ability to have children (fertility). Ask a healthcare provider for advice before taking this medicine

Please see full Prescribing Information for additional Important Safety Information.

Evrysdi® risdiplam

Safety profile

- The most common side effects of Evrysdi include:
  - For later-onset SMA: fever, diarrhea, rash
  - For infantile-onset SMA: fever; diarrhea; rash; runny nose, sneezing, and sore throat (upper respiratory infection); lung infection (lower respiratory infection); constipation; vomiting; cough
- The safety profile of Evrysdi in infants treated before symptoms of SMA appear was consistent with the safety profile of Evrysdi in infants with Type 1 SMA and adults and children with Type 2 or 3 SMA

Talk to your healthcare provider about whether Evrysdi is **right for your family**

Sign up to stay connected

Important Safety Information (continued)

Before taking Evrysdi, tell your healthcare provider about all of your medical conditions, including if you:

- are breastfeeding or plan to breastfeed. It is not known if Evrysdi passes into breast milk and may harm your baby

Tell your healthcare provider about all the medicines you take.

You should receive Evrysdi from the pharmacy as a liquid. If the medicine in the bottle is a powder, **do not use it**. Contact your pharmacist for a replacement.

Avoid getting Evrysdi 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.

The most common side effects of Evrysdi include:

- For later-onset SMA: fever, diarrhea, rash
- For infantile-onset SMA: fever; diarrhea; rash; runny nose, sneezing, and sore throat (upper respiratory infection); lung infection (lower respiratory infection); constipation; vomiting; cough

These are not all of the possible side effects of Evrysdi. For more information on the risk and benefits profile of Evrysdi, ask your healthcare provider or pharmacist.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Genentech at 1-888-835-2555.

Please see full Prescribing Information for additional Important Safety Information.

Genentech
A Member of the Roche Group

Evrysdi® risdiplam