

## The proven efficacy and safety of the liquid formulation

# Now with the flexibility of a tablet<sup>1,2</sup>

The only oral non-invasive treatment for spinal muscular atrophy (SMA) is now approved as 2 formulations for your eligible patients to choose from—liquid or tablet.<sup>2-4\*</sup>



\*Patients must be ≥2 years of age and weigh ≥20 kg (44 lb) to take Evrysdi tablets.²

## Indication

EVRYSDI is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

## **Important Safety Information**

<u>Interactions with Substrates of MATE Transporters</u>

- Based on in vitro data, Evrysdi may increase plasma concentrations of drugs eliminated via MATE1 or MATE2-K. such as metformin
- Avoid coadministration of Evrysdi with MATE (multidrug and toxin extrusion) substrates. If coadministration cannot be avoided, monitor for drug-related toxicities and consider dosage reduction of the coadministered drug if needed

Please see full Prescribing Information for additional Important Safety Information.

## First-in-class tablets built on a heritage of innovation and choice<sup>2,3</sup>

Evrysdi was the first to introduce splice modifying technology to oral SMA treatment, offering more choices to the community. Continuing to evolve, we have created another option in a tablet form with the same demonstrated efficacy and safety as the liquid.<sup>1-3</sup>

## Flexibility means treatment that fits your patients' lifestyles<sup>2</sup>

Evrysdi tablets give your patients<sup>2</sup>:



**Refrigeration-free storage**—tablets don't require refrigeration, so patients have more freedom in how and where they take them



**Flexible oral administration**—tablets can be swallowed whole with water or dispersed with non-chlorinated drinking water (eg, filtered water, bottled water), per patient need and preference



**Simplified dosing**—each tablet contains your patient's dose so they don't need to measure it with a syringe, which may help them stay consistent



## **Important Safety Information (continued)**

Pregnancy & Breastfeeding

- Evrysdi may cause embryofetal harm when administered to a pregnant woman. In animal studies, administration of Evrysdi during pregnancy and/or lactation resulted in adverse effects on development. Advise pregnant women of the potential risk to the fetus
- Pregnancy testing is recommended prior to initiating Evrysdi. Advise female patients to use contraception during treatment with Evrysdi and for at least 1 month after the last dose
- There is a pregnancy exposure registry that monitors pregnancy and fetal/neonatal/infant outcomes in women exposed to Evrysdi during pregnancy. Physicians are encouraged to register patients and pregnant women are encouraged to register themselves by calling <u>1-833-760-1098</u> or visiting <a href="https://www.evrysdipregnancyregistry.com">https://www.evrysdipregnancyregistry.com</a>.
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Evrysdi and any potential adverse effects on the breastfed infant



## Two non-invasive formulation options

to fit individual patient needs<sup>2</sup>

	Liquid For illustrative purposes only	Tablet
Eligibility	<b>No age or weight</b> requirements	Patient must be ≥2 years of age and weigh ≥20 kg (44 lb)
Administration	Taken via <b>oral syringe</b>	Can be <b>swallowed whole with water</b> or <b>dispersed with bottled water</b>
Storage	Refrigerate 36°F to 46°F (2°C to 8°C)	Room temperature 68°F to 77°F (20°C to 25°C)
G- or NG-tube	<b>Can</b> be used with G- or NG-tube	<b>Cannot</b> be used with G- or NG-tube
Dosing	Once daily based on patient's age and weight	5-mg dose once daily
Obtaining Evrysdi	Shipped <b>directly to your patient's door</b> through a specialty pharmacy	

 $G=gastrostomy;\ NG=nasogastric.$ 

See back for frequently asked questions about Evrysdi tablets.

## Offer your patients another choice with Evrysdi tablets<sup>2</sup>

## **Important Safety Information (continued)**

Potential Effects on Male Fertility

• Counsel male patients that fertility may be compromised by treatment with Evrysdi. Male patients may consider sperm preservation prior to treatment

#### Most Common Adverse Reactions

- The most common adverse reactions in later-onset SMA (incidence in at least 10% of patients treated with Evrysdi and more frequent than control) were fever, diarrhea, and rash
- The most common adverse reactions in infantile-onset SMA were similar to those observed in later-onset SMA patients. Additionally, adverse reactions with an incidence of at least 10% were upper respiratory tract infection (including nasopharyngitis, rhinitis), lower respiratory tract infection (including pneumonia, bronchitis), constipation, vomiting, and cough

Please see full <u>Prescribing Information</u> for additional Important Safety Information.

## Frequently asked questions about Evrysdi tablets



## How were Evrysdi tablets studied?

In a bioequivalence study including 48 participants, the Evrysdi tablet formulation was shown to provide comparable risdiplam exposure to the liquid formulation when administered as a swallowed tablet or dispersed with bottled water. The safety profile of Evrysdi tablets was consistent with the safety profile of the liquid formulation.<sup>1</sup>

#### How large is the tablet?

Evrysdi tablets are 6.6 mm (0.25 in) in diameter and 4.1 mm (0.15 in) in height—about the size of a kernel of corn.<sup>5,6</sup>

## Is there a dose titration or washout period needed to switch patients from the liquid formulation to the tablet?

No. Since the products demonstrated comparable bioavailability, patients can switch from the liquid to the tablet without missing a dose.<sup>1</sup>

## Do Evrysdi tablets have a taste?

Evrysdi tablets are film coated and do not have a taste when swallowed whole. However, the Evrysdi tablet dispersion is strawberry flavored, just like the liquid.<sup>2</sup>

## Why can't Evrysdi tablets be chewed, crushed, cut, or dissolved on the tongue?

The film coating on the tablet protects patients from the active ingredients until they are ingested and processed. Chewing, crushing, or otherwise breaking the film coating may result in extended exposure to the active ingredients before ingestion. The safety of Evrysdi tablets was studied when swallowed whole with water and when dispersed with bottled water. The safety of taking Evrysdi tablets any other way is unknown and therefore is not recommended.<sup>1,2,7</sup>

## Can the tablets be stored outside of their original container, in a pill box for example?

No. To avoid exposing the tablets to moisture, keep the tablets in their original container with the desiccant in the cap.<sup>2</sup>

#### Will patients need prior authorization (PA) to switch to Evrysdi tablets from the liquid formulation?

A PA may be required for Evrysdi. Call the patient's insurance provider or MySMA Support™ at 833-EVRYSDI if you have questions about obtaining prior authorization for your patients. Once approved, a 30-day supply of Evrysdi tablets will be shipped directly to your patient's door.

#### If prescribed, could patients get access to both liquid and tablet formulations?

A patient's ability to get coverage for both formulations will depend on their insurance plan. Call MySMA Support if you have questions.

References: 1. Kletzl H, Heinig K, Jaber B, et al. Bioequivalence and food effect assessment for a room-temperature stable risdiplam tablet formulation in healthy volunteers. Presented at: Muscular Dystrophy Association (MDA) Clinical & Scientific Conference; March 3-6, 2024; Orlando, FL. 2. Evrysdi\* (risdiplam) Prescribing Information. Genentech, Inc. 3. Ratni H, Scalco RS, Stephan AH. Risdiplam, the first approved small molecule splicing modifier drug as a blueprint for future transformative medicines. ACS Med Chem Lett. 2021;12(6):874-877.

4. Singh RN, Ottesen EW, Singh NN. The first orally deliverable small molecule for the treatment of spinal muscular atrophy. Neurosci Insights. 2020;15:1-11. 5. Data on file. Genentech USA, Inc. 6. Physical properties of sweet corn seed. ScienceDirect. Accessed October 25, 2024. https://www.sciencedirect.com/science/article/abs/pii/S0260877405001925 7. Pharmaceutical issues when crushing, opening or splitting oral dosage forms. Royal Pharmaceutical Society. June 2011. Accessed January 28, 2025. https://www.rpharms.com/Portals/0/RPS%20 document%20library/Open%20access/Support/toolkit/pharmaceuticalissuesdosageforms-%282%29.pdf

## **Important Safety Information (continued)**

Most Common Adverse Reactions

• The safety profile for presymptomatic patients is consistent with the safety profile for symptomatic SMA patients treated with Evrysdi in clinical trials

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

Please see full <u>Prescribing Information</u> for additional Important Safety Information.



