Evrysdi® risdiplam 60 mg powder for oral solution

EVRYSDI DOSING TABLES

The tables on the following pages can be used to check your work or assist with the following calculations

Daily dose (mg)[1]

For patients **<2 months of age**

0.15 mg/kg ⊗ weight (kg) ⊜ daily dose (mg)

For patients **2 months to 2 years of age**

0.20 mg/kg ⊗ weight (kg) ⊜ daily dose (mg)

For patients ≥**2 years of age**

<20 kg

0.25 mg/kg ⊗ weight (kg) ⊜ daily dose (mg)

≥20 kg

Daily dose ⊜ 5 mg

Dose volume (mL)[1]

Daily dose (mg) ⊕ 0.75 mg/mL ⊜ dose volume (mL)

Reusable oral syringe size (mL)[1,2]

There are 3 syringe sizes available for administration of Evrysdi

1-mL syringe
For doses up to 1 mL
Increments=0.01 mL

6-mL syringe
For doses between 1.0 mL and 6.0 mL
Increments=0.1 mL

12-mL syringe
For doses between 6.2 mL and 6.6 mL
Increments=0.2 mL

Round the dose volume to the closest increment marked on the selected syringe

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

Important Safety Information
Interactions with Substrates of MATE Transporters
- 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.

Age: <2 months | Dose: 0.15 mg/kg[1,2]

Body weight (kg)	Body weight (lb)	Daily dose (mg)	Dose volume* (mL)	Estimated number of daily doses per bottle†	Oral syringe size (mL)
2.00-2.24	4.41-4.94	0.32	0.4	64	1
2.25-2.74	4.96-6.04	0.37	0.5	64	1
2.75-3.24	6.06-7.14	0.45	0.6	64	1
3.25-3.74	7.17-8.25	0.52	0.7	64	1
3.75-4.24	8.27-9.35	0.60	0.8	64	1
4.25-4.74	9.37-10.45	0.67	0.9	64	1
4.75-5.24	10.47-11.55	0.75	1.0	64	1
5.25-5.74	11.57-12.65	0.82	1.1	64	6
5.75-6.24	12.68-13.76	0.90	1.2	64	6
6.25-6.50	13.78-14.33	0.96	1.3	60	6

Questions about Evrysdi?
Contact a Genentech representative.

Learn more

*Dose volumes are rounded to the nearest 0.1 mL. Healthcare professionals have discretion to determine the appropriate volume.
†The estimated number of daily doses assumes proper usage as prescribed. The value is based on a usable volume of 80 mL per bottle.[1,2]

This table is for reference only. The healthcare provider should calculate the correct dose according to the patient's body weight prior to administration.

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 1-833-760-1098 or visiting **https://www.evrysdipregnancyregistry.com**.
- 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

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

Please see full Prescribing Information for additional Important Safety Information.

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Age: 2 months to 2 years | Dose: 0.20 mg/kg[1,2]

Body weight (kg)	Body weight (lb)	Daily dose (mg)	Dose volume (mL)	Estimated number of daily doses per bottle*	Oral syringe size (mL)
3.60-3.93	7.94-8.66	0.75	1.0	64	6
3.94-4.31	8.69-9.50	0.83	1.1	64	6
4.32-4.68	9.52-10.32	0.90	1.2	64	6
4.69-5.06	10.34-11.16	0.98	1.3	60	6
5.07-5.43	11.18-11.97	1.05	1.4	56	6
5.44-5.81	11.99-12.81	1.13	1.5	52	6
5.82-6.18	12.83-13.62	1.20	1.6	49	6
6.19-6.56	13.65-14.46	1.28	1.7	46	6
6.57-6.93	14.48-15.28	1.35	1.8	44	6
6.94-7.31	15.30-16.12	1.43	1.9	41	6
7.32-7.68	16.14-16.93	1.50	2.0	39	6
7.69-8.06	16.95-17.77	1.58	2.1	37	6
8.07-8.43	17.79-18.58	1.65	2.2	36	6
8.44-8.81	18.61-19.42	1.73	2.3	34	6
8.82-9.18	19.44-20.24	1.80	2.4	33	6
9.19-9.56	20.26-21.08	1.88	2.5	31	6
9.57-9.93	21.10-21.89	1.95	2.6	30	6
9.94-10.31	21.91-22.73	2.03	2.7	29	6
10.32-10.68	22.75-23.55	2.10	2.8	28	6
10.69-11.06	23.57-24.38	2.18	2.9	27	6
11.07-11.43	24.41-25.20	2.25	3.0	26	6
11.44-11.81	25.22-26.04	2.33	3.1	25	6
11.82-12.18	26.06-26.85	2.40	3.2	24	6
12.19-12.56	26.87-27.69	2.48	3.3	24	6
12.57-12.93	27.71-28.51	2.55	3.4	23	6
12.94-13.31	28.53-29.34	2.63	3.5	22	6
13.32-13.61	29.37-30.00	2.69	3.6	22	6

Weight ranges may overlap across some tables. Check to ensure you are referencing the correct table based on the patient's age and weight.

*The estimated number of daily doses assumes proper usage as prescribed. The value is based on a usable volume of 80 mL per bottle.[1,2]

This table is for reference only. The healthcare provider should calculate the correct dose according to the patient's body weight prior to administration.

Important Safety Information (continued)

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 Prescribing Information for additional Important Safety Information.

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Age: ≥2 years | Dose: 0.25 mg/kg[1,2]

Body weight (kg)	Body weight (lb)	Daily dose (mg)	Dose volume (mL)	Estimated number of daily doses per bottle*	Oral syringe size (mL)
8.00-8.24	17.64-18.17	2.03	2.7	29	6
8.25-8.54	18.19-18.83	2.10	2.8	28	6
8.55-8.84	18.85-19.49	2.17	2.9	27	6
8.85-9.14	19.51-20.15	2.25	3.0	26	6
9.15-9.44	20.17-20.81	2.32	3.1	25	6
9.45-9.74	20.83-21.47	2.40	3.2	24	6
9.75-10.04	21.50-22.13	2.47	3.3	24	6
10.05-10.34	22.16-22.80	2.55	3.4	23	6
10.35-10.64	22.82-23.46	2.62	3.5	22	6
10.65-10.94	23.48-24.12	2.70	3.6	22	6
10.95-11.24	24.14-24.78	2.77	3.7	21	6
11.25-11.54	24.80-25.44	2.85	3.8	20	6
11.55-11.84	25.46-26.10	2.92	3.9	20	6
11.85-12.14	26.12-26.76	3.00	4.0	19	6
12.15-12.44	26.79-27.43	3.07	4.1	19	6
12.45-12.74	27.45-28.09	3.15	4.2	18	6
12.75-13.04	28.11-28.75	3.22	4.3	18	6
13.05-13.34	28.77-29.41	3.30	4.4	18	6
13.35-13.64	29.43-30.07	3.37	4.5	17	6
13.65-13.94	30.09-30.73	3.45	4.6	17	6
13.95-14.24	30.75-31.39	3.52	4.7	16	6
14.25-14.54	31.42-32.06	3.60	4.8	16	6
14.55-14.84	32.08-32.72	3.67	4.9	16	6
14.85-15.14	32.74-33.38	3.75	5.0	15	6
15.15-15.44	33.40-34.04	3.82	5.1	15	6
15.45-15.74	34.06-34.70	3.90	5.2	15	6
15.75-16.04	34.72-35.36	3.97	5.3	14	6
16.05-16.34	35.38-36.02	4.05	5.4	14	6
16.35-16.64	36.05-36.68	4.12	5.5	14	6
16.65-16.94	36.71-37.35	4.20	5.6	14	6
16.95-17.24	37.37-38.01	4.27	5.7	13	6
17.25-17.54	38.03-38.67	4.35	5.8	13	6
17.55-17.84	38.69-39.33	4.42	5.9	13	6
17.85-18.15	39.35-40.01	4.50	6.0	13	6
18.16-18.75	40.04-41.34	4.61	6.2	12	12
18.76-19.35	41.36-42.66	4.76	6.4	12	12
>19.35-19.99	42.66-44.07	4.92	6.6	12	12
≥20.00	≥44.09	5-mg flat dose	6.6	12	12

Weight ranges may overlap across some tables. Check to ensure you are referencing the correct table based on the patient's age and weight.

*The estimated number of daily doses assumes proper usage as prescribed. The value is based on a usable volume of 80 mL per bottle.[1,2]

This table is for reference only. The healthcare provider should calculate the correct dose according to the patient's body weight prior to administration.

References: 1. Evrysdi® (risdiplam) Prescribing Information. Genentech, Inc. **2.** Evrysdi® (risdiplam) Instructions for Use. Genentech, Inc.

Important Safety Information (continued)

Most Common Adverse Reactions (continued)

- 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 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.

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M-US-00024605(v1.0) 08/24

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