x rivfloza® (nedosiran) injection x0mg, 128mg, 160mg

Rivfloza® dosing and administration guide



Rivfloza[®] is an RNAi therapy designed to reduce levels of hepatic LDH enzyme and reduce the overproduction of oxalate by the liver.¹

LDH=lactate dehydrogenase; RNAi=RNA interference.

Indication and Usage

Rivfloza[®] (nedosiran) injection 80 mg, 128 mg, or 160 mg is indicated to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, eg, eGFR \geq 30 mL/min/1.73 m².

Important Safety Information

Adverse Reactions

Most common adverse reactions (reported in \geq 20% of patients) are injection site reactions, which include erythema, pain, bruising, and rash.

Please see Important Safety Information throughout. Please <u>click here</u> for Rivfloza® Prescribing Information.

Rivfloza® dosing

- Rivfloza[®] is provided as a prefilled syringe (fixed dose) or single-dose vial.¹
- Rivfloza[®] is administered once monthly via subcutaneous injection
- Dosing is based on age and actual body weight
- No loading dose or titration schedule required

Dosing regimen in adults and children aged 12 years and older¹

Body weight	Dosing regimen	
Less than 110 lbs (Less than 50 kg)	128 mg once monthly (prefilled syringe, 0.8 mL)	C C C C C C C C C C C C C C C C C C C
110 lbs and above (50 kg and above)	160 mg once monthly (prefilled syringe, 1 mL)	

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Body weight	Dosing regimen		
Less than 86 lbs (Less than 39 kg)	3.3 mg/kg once monthly, not to exceed 128 mg (Vial, dose volume rounded to nearest 0.1 mL)		
86 to less than 110 lbs (39 to less than 50 kg)	128 mg once monthly (prefilled syringe, 0.8 mL)		
110 lbs and above (50 kg and above)	160 mg once monthly (prefilled syringe, 1 mL)		
When administering Rivfloza [®] using the single-dose vial , use 2 Rivfloza [®] vials if the prescribed dose is			

Missed doses¹

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0.6 mL or more.

- In the case of a missed dose, administer Rivfloza[®] as soon as possible
- If the planned dose is missed by >7 days, administer Rivfloza[®] as soon as possible and resume monthly dosing from the most recently administered dose

rivfloza[®] (nedosiran) injection ^{80mg, 128mg, 160mg}

Dosing regimen in children aged 2 to less than 12 years¹

Rivfloza® administration



At-home administration

After proper training:

 Rivfloza[®] can be self-administered or caregiveradministered at home via single-dose prefilled syringe or vial¹



Prefilled syringe

- For patients aged 12 years and older, the patient, caregiver, or a healthcare provider may administer Rivfloza[®] using the prefilled syringe¹
- For children aged 2 to less than 12 years who weigh 86 lbs and above (39 kg and above), a caregiver or healthcare provider may administer Rivfloza[®] using the prefilled syringe¹

See Rivfloza[®] *Instructions for Use* for **single-dose**, **prefilled syringe** in <u>Prescribing Information</u>.



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Single-dose vial

- Rivfloza[®] single-dose vials are intended for use under the **guidance and supervision** of a healthcare provider¹
- For children aged 2 to less than 12 years who weigh less than 86 lbs (less than 39 kg), Rivfloza[®] may be administered from a vial by a caregiver after proper training, if a healthcare provider determines that it is appropriate, and with medical follow-up as necessary¹



Rivfloza[®] storage and handling

Rivfloza[®] is available in single-dose prefilled syringes and single-dose vials in cartons.¹



Storage conditions¹

Refrigerated 36 °F to 46 °F (2 °C to 8 °C)		Room temperature 59 °F to 86 °F (15 °C to 30 °C)		
Until expiration date		Maximum 28 days (4 weeks)		
	Do not freeze Rivfloza®			
	Store in original carton, away from direct heat and light			
R	Rivfloza® vials are for one-time use only. Do not reuse the Rivfloza® vial and discard any unused medication			
Important Safety Information				

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Reference: 1. Rivfloza[®] [package insert]. Plainsboro, NJ: Novo Nordisk Inc.

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