Viltepso™
(viltolarsen) injection

VILTEPSO FOR PATIENTS WITH DUCHENNE MUSCULAR DYSTROPHY (DMD) AMENABLE TO EXON 53 SKIPPING

Quick Reference for VILTEPSO Infusion

Indication

VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VILTEPSO.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information

- **Warnings and Precautions:** In clinical studies, no patients experienced kidney toxicity during treatment with VILTEPSO. However, kidney toxicity from drugs like VILTEPSO may be possible. Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting and during treatment with VILTEPSO. Consider measuring GFR before starting VILTEPSO.
- **Adverse Reactions:** The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

VILTEPSO Offers a Choice of Treatment Location—at Home or at a Treatment Center

VILTEPSO is given as an 80-mg/kg weekly **intravenous infusion**

The **appropriate dose** of VILTEPSO is calculated based upon **patient weight**, at a recommended weekly dosage of 80 mg/kg

VILTEPSO is infused over **60 minutes** by a healthcare professional at home or at a treatment center

How to Store and Handle VILTEPSO

VILTEPSO should be stored according to the procedures outlined below:

Store VILTEPSO at 2°C to 8°C (36°F to 46°F)

Do not freeze

For more information about VILTEPSO, see accompanying full Prescribing Information.

Necessary Steps for Preparing VILTEPSO for Infusion

- Complete the dosing calculation or consult the dosage chart
- Allow vials to warm to room temperature. Mix the contents of each vial by gently inverting 2 to 3 times. Do not shake
- Visually inspect each vial of VILTEPSO. VILTEPSO is a clear and colorless solution. Do not use if the solution in the vials is discolored or particulate matter is present

When <20 vials (ie, <100 mL) of VILTEPSO are required:

1. **Withdraw from the 100-mL infusion bag a volume of 0.9% Sodium Chloride Injection, USP, equivalent to the calculated volume of VILTEPSO solution that will be added.**
2. **Withdraw the calculated volume of VILTEPSO solution from the appropriate number of vials, and inject into the infusion bag, such that the total volume in the bag is 100 mL.**

When ≥20 vials (ie, ≥100 mL) of VILTEPSO are required:

1. **Withdraw the calculated volume of VILTEPSO solution from the appropriate number of vials, and inject into an empty infusion bag. Further dilution is not required if the volume of VILTEPSO is 100 mL or more.**

Visually inspect the infusion bag containing the solution for particulates. Gently invert the infusion bag to ensure equal distribution of product. Do not shake.

After Preparation, VILTEPSO Infusion Should Begin as Soon as Possible

Infusion should begin no more than 5 hours after preparation of VILTEPSO and be completed within 6 hours of preparation (allowing for 1 hour of infusion time) if diluted solution is stored at 20°C to 26°C (68°F to 79°F)

If immediate use is not possible, the VILTEPSO solution may be stored for up to 24 hours at 2°C to 8°C (36°F to 46°F). Do not freeze.

VILTEPSO is administered via intravenous infusion using a peripheral or central venous catheter. Flush the intravenous access line with 0.9% Sodium Chloride Injection, USP, after infusion. Filtration of VILTEPSO is not required

Do not mix other medications with VILTEPSO or infuse other medications concomitantly via the same intravenous access line

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- **Adverse Reactions:** The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

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Weekly Dosage Chart

Only odd kg body weight provided for illustrative purposes.

The dose will be prepared based on the patient's body weight. Each 5 mL VILTEPSO vial contains 250 mg of viltolarsen. The number of VILTEPSO vials required for patients with body weights from 15.0 to 69.0 kg to provide a dose of 80 mg/kg/wk is presented in the chart below.

Body Weight (kg)	Body Weight (lb)	Total VILTEPSO Dose (mg)	Theoretical Number of Vials Required (vial)	Whole Number of Vials Required (vial)	Volume of Saline Retained in Infusion Bag[a] (mL)	Volume of VILTEPSO Injected into Infusion Bag (mL)	Total Volume of VILTEPSO Solution in Infusion Bag (mL)
15.0	33.0	1200	4.8	5	76.0	24.0	100.0
17.0	37.4	1360	5.4	6	72.8	27.2	100.0
19.0	41.8	1520	6.1	7	69.6	30.4	100.0
21.0	46.2	1680	6.7	7	66.4	33.6	100.0
23.0	50.6	1840	7.4	8	63.2	36.8	100.0
25.0	55.0	2000	8.0	8	60.0	40.0	100.0
27.0	59.4	2160	8.6	9	56.8	43.2	100.0
29.0	63.8	2320	9.3	10	53.6	46.4	100.0
31.0	68.2	2480	9.9	10	50.4	49.6	100.0
33.0	72.6	2640	10.6	11	47.2	52.8	100.0
35.0	77.0	2800	11.2	12	44.0	56.0	100.0
37.0	81.4	2960	11.8	12	40.8	59.2	100.0
39.0	85.8	3120	12.5	13	37.6	62.4	100.0
41.0	90.2	3280	13.1	14	34.4	65.6	100.0
43.0	94.6	3440	13.8	14	31.2	68.8	100.0
45.0	99.0	3600	14.4	15	28.0	72.0	100.0
47.0	103.4	3760	15.0	16	24.8	75.2	100.0
49.0	107.8	3920	15.7	16	21.6	78.4	100.0
51.0	112.2	4080	16.3	17	18.4	81.6	100.0
53.0	116.6	4240	17.0	17	15.2	84.8	100.0
55.0	121.0	4400	17.6	18	12.0	88.0	100.0
57.0	125.4	4560	18.2	19	8.8	91.2	100.0
59.0	129.8	4720	18.9	19	5.6	94.4	100.0
61.0	134.2	4880	19.5	20	2.4	97.6	100.0
63.0	138.6	5040	20.2	21	–	100.8	100.8
65.0	143.0	5200	20.8	21	–	104.0	104.0
67.0	147.4	5360	21.4	22	–	107.2	107.2
69.0	151.8	5520	22.1	23	–	110.4	110.4

[a]If the volume of VILTEPSO required is <100 mL (<20 vials of VILTEPSO), dilution in 0.9% Sodium Chloride Injection, USP is required such that the total volume in the infusion bag is 100 mL. If the volume of VILTEPSO to be infused is ≥100 mL (≥20 vials of VILTEPSO), dilution is not required.

For more information about VILTEPSO, see accompanying full Prescribing Information.

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NOTES

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