# VILTEPSO DOSING POCKET GUIDE

VILTEPSO is given as an 80-mg/kg weekly **intravenous (IV) infusion**[1]

The **appropriate dose** of VILTEPSO is calculated based upon **patient weight**, at a recommended weekly dosage of 80 mg/kg[1]

VILTEPSO is infused for **60 minutes** by a healthcare professional, at home or at a treatment center[1]

**To calculate an appropriate dose of VILTEPSO based on a patient's weight, please see the chart inside**

## 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:** Kidney toxicity was observed in animals who received viltolarsen. Although kidney toxicity was not observed in the clinical studies with VILTEPSO, the clinical experience with VILTEPSO is limited, and kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Kidney function should be monitored in patients taking VILTEPSO. Serum creatinine may not be a reliable measure of kidney function in DMD patients.

**Please see Important Safety Information throughout.**
**For additional information about VILTEPSO, see accompanying full Prescribing Information.**

Viltepso®
(viltolarsen) injection

# Weekly dosing chart[1]

*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/5 mL (50 mg/mL) of viltolarsen. The number of VILTEPSO vials required for patients with body weights from 15.0 kg to 69.0 kg to provide a dose of 80 mg/kg/wk is presented in the chart at right.

| Body weight (kg) | Body weight (lb) | VI |
|---|---|---|
| 15.0 | 33.0 | |
| 17.0 | 37.4 | |
| 19.0 | 41.8 | |
| 21.0 | 46.2 | |
| 23.0 | 50.6 | |
| 25.0 | 55.0 | |
| 27.0 | 59.4 | |
| 29.0 | 63.8 | |
| 31.0 | 68.2 | |
| 33.0 | 72.6 | |
| 35.0 | 77.0 | |
| 37.0 | 81.4 | |
| 39.0 | 85.8 | |
| 41.0 | 90.2 | |
| 43.0 | 94.6 | |
| 45.0 | 99.0 | |
| 47.0 | 103.4 | |
| 49.0 | 107.8 | |
| 51.0 | 112.2 | |
| 53.0 | 116.6 | |
| 55.0 | 121.0 | |
| 57.0 | 125.4 | |
| 59.0 | 129.8 | |
| 61.0 | 134.2 | |
| 63.0 | 138.6 | |
| 65.0 | 143.0 | |
| 67.0 | 147.4 | |
| 69.0 | 151.8 | |

*If volume of VILTEPSO requi
100 mL. If the volume of VIL
†The actual number of theor

## Necessary steps for preparing VILTEPSO for infusion[1]

- 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

**Please see Important Safety Information throughout. For additional information about VILTEPSO, see accompanying full Prescribing Information.**

## 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).[1]

VILTEPSO is administered via IV infusion using a peripheral or central venous catheter. Flush the IV access line with 0.9% sodium chloride for injection, USP, after infusion. Filtration of VILTEPSO is not required.[1]

Do not mix other medications with VILTEPSO or infuse other medications concomitantly via the same IV access line.[1]

USP=United States Pharmacopeia.

## Important Safety Information

**Warnings and Precautions (continued):** Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting VILTEPSO. Consider also measuring glomerular filtration rate before starting VILTEPSO. During treatment, monitor urine dipstick every month, and serum cystatin C and urine protein-to-creatinine ratio every three months.

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# Weekly dosing chart[1]

*Only odd kg body weight provided for illustrative purposes.*

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| 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* (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 |

*If volume of VILTEPSO required is <100 mL, dilution in 0.9% sodium chloride for 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, dilution is not required.

†The actual number of theoretical vials required is 15.04.

## Necessary steps for preparing VILTEPSO for infusion[1]

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- 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

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

### When less than 100 mL of VILTEPSO is required:

1. Withdraw from the 100-mL infusion bag a volume of 0.9% sodium chloride injection for 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 100 mL or more of VILTEPSO is required:

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.

**Please see Important Safety Information throughout. For additional information about VILTEPSO, see accompanying full Prescribing Information.**

Viltepso® (viltolarsen) injection

NOTES

**If you have questions about VILTEPSO, please contact your VILTEPSO representative, or visit VILTEPSO.com**

## Important Safety Information

**Warnings and Precautions (continued):** Urine should be free of excreted VILTEPSO for monitoring of urine protein. Obtain urine either prior to VILTEPSO infusion, or at least 48 hours after the most recent infusion. Alternatively, use a laboratory test that does not use the reagent pyrogallol red, which has the potential to generate a false positive result due to cross reaction with any VILTEPSO in the urine. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

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

**Please see Important Safety Information throughout.**
**For additional information about VILTEPSO, see accompanying full Prescribing Information.**

**Reference: 1.** Viltepso [prescribing information]. Paramus, NJ: NS Pharma, Inc.; 2021.

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12/21 US-NS65C-0820

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