Viltepso®
(viltolarsen) injection

Dosing & administration guide

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.

HOW TO INITIATE TREATMENT

Download the Patient Start Form at VILTEPSO.com
Contact NS Support:
Phone: 833-NSSUPRT (833-677-8778) Fax: 888-212-0482

NS Support
NS PHARMA ACCESS SOLUTIONS

Patient Start Form

MAIL or FAX completed Start Form to NS Support

MAIL OR FAX THE COMPLETED FORM TO:
NS Support Program, PO Box 29203, Phoenix, AZ 85038-9203, Phone: 833-NSSUPRT (833-677-8778), Fax: 888-212-0482

1. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE INFORMATION

PATIENT NAME (First, MI, Last) _____ DOB (MM/DD/YYYY) _____
ADDRESS _____ CITY _____ STATE _____ ZIP _____
PRIMARY CONTACT NAME _____ RELATIONSHIP TO PATIENT _____
EMAIL _____ PREFERRED PHONE # _____ ❑ Home ❑ Cell ❑ Other

2. INSURANCE INFORMATION

Complete all information requested below.

PRIMARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____
SECONDARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____
❑ **Check if you are including a copy of the front and back of the patient's insurance card(s) or face sheet.**

3. PHYSICIAN INFORMATION

NAME (First, Last) _____ FACILITY NAME _____
ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____
NPI # _____ TAX ID # (optional) _____ OFFICE CONTACT _____
PHONE _____ FAX _____ EMAIL _____

4. PREFERRED SITE OF CARE (OPTIONAL)

Check all that apply.

❑ Hospital Clinic ❑ Home Infusion ❑ Physician's Office ❑ Other ❑ Needs Site of Care Identification
PREFERRED PROVIDER(s) (If Available) _____

5. PHYSICIAN DECLARATION

A physician's signature is required in order for NS Support to perform a benefits verification.

By signing below, I certify that (1) the therapy is medically necessary and in the best interest of the patient identified above; (2) the patient is appropriately indicated for G71.01 Duchenne muscular dystrophy; and (3) I have obtained and provide any consent required under federal and state law for the release and use of the patient's information on this form to NS Pharma, Inc. and its agents, including its commercial and field-based teams, for purposes of benefits verification and coordination of dispensing the therapy.

PHYSICIAN NAME (Please Print) _____
PHYSICIAN SIGNATURE _____ DATE _____

6. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

NS Support will contact the patient if physician is unable to obtain patient's signature.

By signing below, I certify and acknowledge that I have read, understand, and agree to the Patient/Parent/Guardian/Legal Representative Authorization on page 2 of this form, for the patient to participate in the NS Support Program, and to release the patient's Protected Health Information to NS Pharma, Inc. (as defined on page 2 of this form), supporting the access program as indicated on the Patient/Legal Guardian Authorization.

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) SIGNATURE _____ DATE _____
PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) PRINT NAME _____
RELATIONSHIP TO PATIENT _____

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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.

DOSING

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

- VILTEPSO can be administered using either a peripheral or central venous catheter

Calculate the appropriate dose of VILTEPSO based on patient weight[1]

Calculate the dose based on the patient's weight and the recommended dose of 80 mg/kg

80 mg/kg × patient's weight (in kg) = total dose of VILTEPSO (in mg) needed each week

For example, a 35-kg child will need 2800 mg of VILTEPSO (35 kg × 80 mg/kg)

Calculate the volume needed based on the concentration in a single-dose 50-mg/mL vial

[80 mg/kg × patient's weight in kg] ÷ 50 mg/mL = volume of VILTEPSO (in mL) needed

For example, a 35-kg child will need 56 mL of VILTEPSO (35 kg × 80 mg/kg ÷ 50 mg/mL)

Note: If the volume of required VILTEPSO is less than 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.

PLEASE SEE THE WEEKLY DOSING CHARTS FOR ODD BODY WEIGHTS-BASED CALCULATIONS ON THE NEXT PAGE

USP=United States Pharmacopeia.

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WEEKLY DOSING CHART[1]

Only odd kg body weight provided for illustrative purposes.

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.

When less than 100 mL of VILTEPSO is required:

1. Withdraw from the 100-mL infusion bag a volume of 0.9% sodium chloride 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.

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PREPARATION AND ADMINISTRATION

VILTEPSO is supplied in single-dose (250-mg/5-mL) vials in a clear, colorless, preservative-free solution[1]

- Visually inspect each vial. Do not use if the solution in the vials is discolored or particulate matter is present
- Allow the vials to warm to room temperature
- Mix the contents gently by inverting 2 to 3 times. Do not shake

Prepare the VILTEPSO solution for infusion using aseptic technique[1]

If **less than 100 mL** of VILTEPSO is required:

1. Withdraw the calculated volume of VILTEPSO from the appropriate number of vials
2. From a 100-mL infusion bag of 0.9% sodium chloride for injection, USP, withdraw a volume that is equivalent to the calculated volume of VILTEPSO
3. Inject VILTEPSO into the infusion bag
4. Visually inspect the infusion bag for particulates
5. Gently invert the infusion bag to ensure equal distribution. Do not shake
6. Discard unused VILTEPSO

If **100 mL or more** of VILTEPSO is required, no additional dilution with 0.9% sodium chloride for injection, USP is required, and the required amount of VILTEPSO should be placed into an empty infusion bag. Visually inspect the infusion bag for particulates. Gently invert the infusion bag.

Selecting a comfortable needle size may help reduce injection discomfort[2,3]

It should take 60 minutes to complete IV infusion of VILTEPSO[1]

- Begin infusion as soon as possible—no more than 5 hours after preparation—and complete within 6 hours of preparation if diluted solution is stored at 20° C to 26° C (68° F to 79° F)
- Do not mix other medications with VILTEPSO or infuse other medications concomitantly via the same IV access line
- Flush the IV access line with 0.9% sodium chloride for injection, USP, after infusion

If injection site reaction or post-infusion low-grade fever occurs, patients may be managed on-site or at home with appropriate management techniques, including[4]:

- Over-the-counter pain relievers
- Antihistamines
- Antipyretics
- Cold compresses

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.

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VILTEPSO offers a choice of treatment location—at home or at a treatment center

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

Download the Patient Start Form at **VILTEPSO.com** to get your patients initiated on treatment

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

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 more information about VILTEPSO, see accompanying full Prescribing Information.

References: 1. Viltepso [prescribing information]. Paramus, NJ: NS Pharma, Inc.; 2021. **2.** Gill HS, Prausnitz MR. Does needle size matter? *J Diabetes Sci Technol*. 2007;1(5):725-729. **3.** Aronson R. The role of comfort and discomfort in insulin therapy. *Diabetes Technol Ther*. 2012;14(8):741-747. **4.** Cole B. Injection-site reactions and how to manage them. *Pharmacy Times*. 2019;1(5):1-11.

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