For the treatment of DMD in patients amenable to exon 53 skipping[1]

VILTEPSO 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 no patients experienced kidney toxicity during treatment 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. Because of the effect of reduced skeletal muscle mass on creatinine measurements, serum creatinine may not be a reliable measure of kidney function in DMD patients. 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.

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

Viltepso®
(viltolarsen) injection

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 upon 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: 35 kg x 80 mg = 2800 mg of VILTEPSO
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 = volume of VILTEPSO (in mL) needed **For example**, a 35-kg child will need: 35 kg x 80 mg ÷ 50 = 56 mL of VILTEPSO

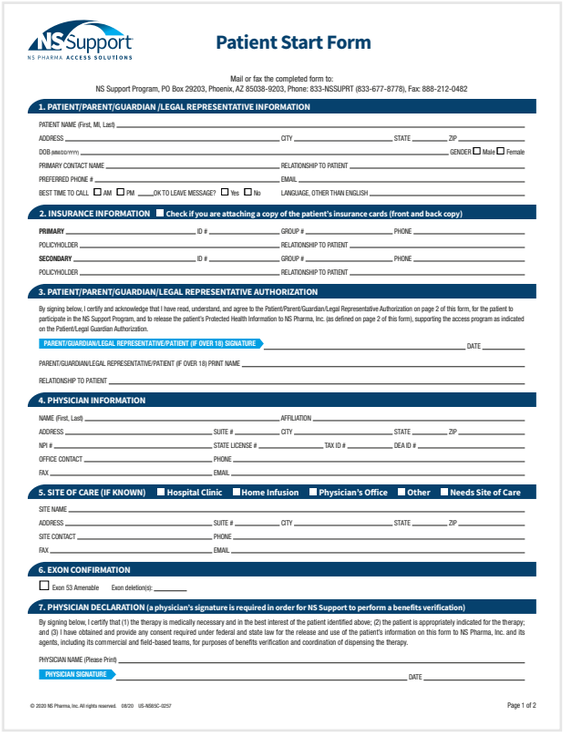
Note: If the volume of required VILTEPSO is less than 100 mL, dilution in 0.9% Sodium Chloride Injection, USP is required such that the total volume in the infusion bag is 100 mL.

USP=United States Pharmacopeia.

For more 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 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) _____
ADDRESS _____ CITY _____ STATE _____ ZIP _____
DOB (MM/DD/YYYY) _____ GENDER ☐ Male ☐ Female
PRIMARY CONTACT NAME _____ RELATIONSHIP TO PATIENT _____
PREFERRED PHONE # _____ EMAIL _____
BEST TIME TO CALL ☐ AM ☐ PM ____OK TO LEAVE MESSAGE? ☐ Yes ☐ No LANGUAGE, OTHER THAN ENGLISH _____

2. INSURANCE INFORMATION ☐ Check if you are attaching a copy of the patient's insurance cards (front and back copy)

PRIMARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____
SECONDARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____

3. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

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.

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

4. PHYSICIAN INFORMATION

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

5. SITE OF CARE (IF KNOWN) ☐ Hospital Clinic ☐ Home Infusion ☐ Physician's Office ☐ Other ☐ Needs Site of Care

SITE NAME _____
ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____
SITE CONTACT _____ PHONE _____
FAX _____ EMAIL _____

6. EXON CONFIRMATION

☐ Exon 53 Amenable Exon deletion(s): _____

7. 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 the therapy; 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 _____

Important Safety Information

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

Please see additional Important Safety Information throughout.

Viltepso®
(viltolarsen) injection

ADMINISTRATION

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

- Inspect each vial for particulate matter and discoloration prior to preparation
- 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 the volume of VILTEPSO required is **less than 100 mL**:

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 Injection, USP, withdraw a volume that is equivalent to the calculated volume of VILTEPSO and discard
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 the volume of VILTEPSO required is **≥100 mL**, no additional dilution with 0.9% Sodium Chloride 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 to ensure equal distribution. Do not shake. Discard unused VILTEPSO.

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Please see additional Important Safety Information throughout.

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

- VILTEPSO should only be mixed with 0.9% Sodium Chloride, USP, if further dilution is required
- Do not mix other medications with VILTEPSO or infuse other medications concomitantly via the same IV access line
- 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)
- If immediate use is not possible, the solution may be stored for up to 24 hours at 2° C to 8° C (36° F to 46° F). Do not freeze
- Flush the IV access line with 0.9% Sodium Chloride Injection, USP, after infusion. Filtration of VILTEPSO is not required

Contact your VILTEPSO representative or visit VILTEPSO.com for additional information and resources

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

Viltepso® (viltolarsen) injection

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]

Visit VILTEPSO.com to download the Patient Start Form and get your patients initiated on treatment

Indication

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

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