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MADISON NEUROLOGY LLC

608 403 0000

Neurology Care 7 days a Week. Because Your Brain Matters.

Viltepso®

Viltolarsen

COMPLETE CLINICAL PROTOCOL: PRE-TREATMENT CHECKLIST • ORDER SET • FOLLOW-UP • HOLD/DISCONTINUE CRITERIA

GENERIC NAME	viltolarsen
BRAND	VILTEPSO®
MEDICATION CLASS	Antisense oligonucleotide (phosphorodiamidate morpholino oligomer, exon 53 skipping)
PRESENTATION	250 mg/5 mL (50 mg/mL) single-dose vial — dilute in 0.9% NaCl
ROUTE	IV infusion over 60 minutes, once weekly
US INDICATION (FDA)	Duchenne muscular dystrophy in patients with a CONFIRMED mutation amenable to exon 53 skipping (accelerated approval based on dystrophin increase).

Class context.
Same exon-53 target as golodirsen but a DIFFERENT per-kg dose (80 vs 30 mg/kg) — the products are not interchangeable mg-for-mg; verify the product name on every order.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ Genetic confirmation of an exon 53–amenable DMD mutation — REQUIRED.

☐ Renal baseline: creatinine, cystatin C (preferred in DMD), BUN, urine dipstick.

☐ Baseline motor function and corticosteroid-regimen documentation.

B. Vaccinations

☐ No label restrictions.

C. Clinical assessments & counseling

☐ Baseline motor assessment; sustainable weekly-access plan.

☐ Hypersensitivity counseling.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
Mutation not amenable to exon 53 skipping	Not the labeled population.
Serious hypersensitivity to viltolarsen	Do not administer.

Section 2 — Order Set

Premedication

☐ None required; premedicate after prior hypersensitivity per institutional practice.

Dosing schedule

Standard dose	80 mg/kg IV once weekly over 60 minutes.

Standing orders — every infusion

☐ Hypersensitivity monitoring each infusion; periodic weight checks for weight-based dosing.

Missed or delayed dose

Give a missed dose as soon as possible; resume the weekly schedule.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Renal function — cystatin C, creatinine, BUN, urine dipstick	Baseline, then periodically	Deterioration → hold and evaluate.
Motor function	Every 6–12 months	Continuation documentation.
Hypersensitivity review	Every infusion	Anaphylaxis → discontinue.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Renal signal	Hold and evaluate.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Anaphylaxis or serious hypersensitivity	Discontinue.
Progressive renal toxicity attributed to therapy	Discontinue; specialist review.

Section 5 — Notes & Practical Points

☐ Accelerated approval on a dystrophin surrogate; confirmatory evidence still required.

☐ 80 mg/kg ≠ 30 mg/kg: always confirm WHICH exon-53 product is on the order.

Prepared November 2026 by Madison Neurology LLC.

This document is an educational compilation and does not reproduce the complete prescribing information. Verify every element against the current FDA label and applicable REMS requirements before clinical use.

- Current U.S. prescribing information via NIH DailyMed — https://dailymed.nlm.nih.gov/dailymed/
- FDA Drugs@FDA database — https://www.accessdata.fda.gov/scripts/cder/daf/
- FDA drug safety and availability updates — https://www.fda.gov/drugs/drug-safety-and-availability

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Questions about infusion referrals: call 608 403 0000. Neurology Care 7 days a Week. Because Your Brain Matters.