MADISON NEUROLOGY LLC

608 403 0000

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

Radicava®

Edaravone (IV formulation)

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

GENERIC NAME	edaravone (IV formulation)
BRAND	RADICAVA®
MEDICATION CLASS	Free-radical scavenger
PRESENTATION	60 mg/100 mL (0.6 mg/mL) ready-to-infuse bag; also 30 mg/100 mL — do NOT dilute further
ROUTE	IV infusion over 60 minutes
US INDICATION (FDA)	Treatment of amyotrophic lateral sclerosis (ALS).

Class context.
The dominant practical constraint is the daily-visit burden (cycle 1 = 14 consecutive daily visits). The oral suspension (same active drug) exists precisely for this reason — route selection is a logistics decision as much as a clinical one.

Section 1 — Pre-Treatment Checklist

A. Required screening labs

☐ Confirm ALS diagnosis and document baseline function (ALSFRS-R).

☐ SULFITE-sensitivity review: edaravone contains sodium bisulfite — allergic-type reactions (including anaphylaxis) can occur; use particular caution in asthma.

☐ Hypersensitivity history (edaravone hypersensitivity, including anaphylaxis, is labeled).

☐ Pregnancy test when relevant.

B. Vaccinations

☐ No label restrictions.

C. Clinical assessments & counseling

- ☐ Plan the daily-infusion logistics BEFORE committing to the IV route: cycle 1 = 14 consecutive daily visits; later cycles = 10 daily visits out of each 14-day window, then 14 days off. Confirm transport, weekend coverage, and scheduling feasibility.
- ☐ Hypersensitivity education: report redness, wheals, breathing symptoms immediately.

D. Exclusion / hold criteria — do not start

CRITERION	RATIONALE / REQUIRED ACTION
History of hypersensitivity to edaravone	Do not administer.
Severe sulfite allergy / brittle asthma	Risk review before choosing the IV formulation.

Section 2 — Order Set

Premedication

- ☐ None required.

Dosing schedule

First treatment cycle	60 mg IV over 60 minutes once daily × 14 consecutive days, followed by a 14-day drug-free period.
Subsequent cycles	60 mg IV over 60 minutes once daily × 10 days out of each 14-day period, followed by a 14-day drug-free period.
Observation	Monitor during and after each infusion for hypersensitivity; anaphylaxis capability must be available.

Standing orders — every infusion

- ☐ Track each cycle's day-count — complete the 14 (first cycle) or 10-of-14 (later cycles) doses before the drug-free period.
- ☐ Hypersensitivity review at every visit; periodic ALSFRS-R for trajectory documentation.

Missed or delayed dose

Administer missed daily doses within the cycle window as scheduled; never double doses; complete each cycle's day-count before the drug-free period.

Section 3 — Follow-Up Protocol

ITEM	FREQUENCY / TIMING	ACTION / THRESHOLD
Hypersensitivity review	Every infusion	Anaphylaxis → discontinue.

Functional status (ALSFRS-R)	Every 1–3 months	Trajectory documentation for continuation reviews.
Respiratory function	Per ALS clinic schedule	Disease surveillance.
Route-review (IV vs oral suspension)	After cycle 1 and periodically	Burden-driven switch is common and legitimate.

Section 4 — Pause vs. Stop Criteria

A. Pause or delay (resume when resolved)

CRITERION	REQUIRED ACTION
Intercurrent illness making daily visits unsafe	Hold; resume per cycle rules.

B. Discontinue permanently

CRITERION	REQUIRED ACTION
Anaphylaxis or serious hypersensitivity	Discontinue.
Patient/family decision as disease progresses	Revisit the oral route before abandoning therapy entirely.

Section 5 — Notes & Practical Points

☐ Coordinate cycle calendars with the ALS clinic — the 14-day drug-free window is part of the regimen, not a lapse.

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.