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on Drugs and Therapeutics

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Online Article

IN THIS ISSUE

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IN BRIEF

Edaravone Oral Suspension *(Radicava ORS)* for ALS

Radicava ORS, an oral suspension formulation of the free radical scavenger edaravone (Mitsubishi Tanabe Pharma), has been approved by the FDA for treatment of amyotrophic lateral sclerosis (ALS). An IV formulation of edaravone *(Radicava)* has been available since 2017.[1]

CLINICAL STUDIES — No new clinical trials were required for FDA approval of oral edaravone; approval was based on the results of a previous study with IV edaravone and a pharmacokinetic study showing that the bioavailability of a 105-mg dose of the oral suspension is similar to that of a 60-mg IV dose.[2]

A retrospective cohort study found that use of IV edaravone in patients with ALS was associated with 6 months' longer median overall survival compared to controls.[3]

An open-label extension study evaluating use of oral edaravone for a total of 3 years' duration is expected to be completed in 2023.

ADVERSE EFFECTS — Adverse effects of edaravone include contusion, gait disturbance, headache, and fatigue. Both the IV and oral formulations contain sodium bisulfite, which can cause hypersensitivity reactions in patients with sulfite allergy.

DOSAGE, ADMINISTRATION, AND COST — *Radicava ORS* is supplied in 35- and 50-mL bottles containing 105 mg/5 mL of edaravone. The recommended dose is 105 mg administered orally or via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tube in the morning following an overnight fast of at least 8 hours. Patients should not consume any food or drink except water for 1 hour after taking the drug. Edaravone oral suspension should be taken once daily for 14 days, followed by 14 days off for the first cycle; for subsequent cycles, it should be taken once daily for 10 days out of 14, followed by 14 days off.

Four weeks of maintenance treatment with *Radicava ORS* costs about $12,720; a four-week supply of the IV formulation costs about $12,230.[4] ■

1. Edaravone (Radicava) for ALS. Med Lett Drugs Ther 2017; 59:180.
2. H Shimizu et al. Bioequivalence study of oral suspension and intravenous formulation of edaravone in healthy adult subjects. Clin Pharmacol Drug Dev 2021; 10:1188.
3. BR Brooks et al. Intravenous edaravone treatment in ALS and survival: an exploratory, retrospective, administrative claims analysis. EClinicalMedicine 2022; 52:101590.
4. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. August 5, 2022. Reprinted with permission by First Databank, Inc. All rights reserved. ©2022. www.fdbhealth.com/policies/drug-pricing-policy.

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