

The Medical Letter[®]

on Drugs and Therapeutics

Volume 64

Published online August 31, 2022

Online
Article

IN THIS ISSUE

Edaravone Oral Suspension (*Radicava ORS*) for ALS

Important Copyright Message

FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. and international copyright laws. Forwarding, copying or any distribution of this material is prohibited.

Sharing a password with a non-subscriber or otherwise making the contents of this site available to third parties is strictly prohibited.

By accessing and reading the attached content I agree to comply with U.S. and international copyright laws and these terms and conditions of The Medical Letter, Inc.

For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)
or call customer service at: 800-211-2769

The Medical Letter®

on Drugs and Therapeutics

Volume 64

Published online August 31, 2022

Online
Article

IN THIS ISSUE

Edaravone Oral Suspension (*Radicava ORS*) for ALS

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.

PRESIDENT: Mark Abramowicz, M.D.; **VICE PRESIDENT, EDITOR IN CHIEF:** Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D. **CONSULTING EDITORS:** Joanna Esterow, PA-C, Mordechai Sacks, DMSc, PA-C, Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

CONTRIBUTING EDITORS: Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Ericka L. Crouse, Pharm.D., B.C.P.P., C.G.P., F.A.S.H.P., F.A.S.C.P., Virginia Commonwealth University; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Albert Einstein College of Medicine; David N. Juurlink, BPhM, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; Neal H. Steigbigel, M.D., New York University School of Medicine; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

MANAGING EDITOR AND DIRECTOR OF CONTENT OPERATIONS: Susie Wong; **EDITORIAL ASSISTANT:** Karrie Ferrara

FULFILLMENT AND SYSTEMS MANAGER: Cristine Romatowski; **EXECUTIVE DIRECTOR OF SALES:** Elaine Reaney-Tomaselli
EXECUTIVE DIRECTOR OF MARKETING AND COMMUNICATIONS: Joanne F. Valentino; **INTERIM PUBLISHER:** Jean-Marie Pflomm, Pharm.D.

Founded in 1959 by Arthur Kallet and Harold Aaron, M.D.

Copyright and Disclaimer: The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. does not sell advertising or receive any commercial support. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The editors do not warrant that all the material in this publication is accurate and complete in every respect. The editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

Subscription Services

Address:

The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:

Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:

To reproduce any portion of this issue,
please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):

1 year - \$159; 2 years - \$298;
3 years - \$398. \$65 per year
for students, interns, residents,
and fellows in the US and Canada.
Reprints - \$45 per issue or article

Site License Inquiries:

E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk
subscriptions.

Get Connected:    

Copyright 2022. ISSN 0025-732X

The
Medical
Letter