Radicava ORS®
(edaravone) Oral Suspension 105mg/5mL

FREQUENTLY ASKED QUESTIONS

Get answers to some of the most common questions about RADICAVA ORS

For appropriate patients,
initiate treatment with RADICAVA ORS upon diagnosis[1]

INDICATION

RADICAVA ORS® (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

RADICAVA ORS® (edaravone) is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred.

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Table of contents

IMPORTANT SAFETY INFORMATION

Sulfite Allergic Reactions

RADICAVA ORS contains sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Clinical experience

Q How was the efficacy of RADICAVA ORS determined?

The efficacy of RADICAVA ORS was based on the pivotal clinical trial for RADICAVA IV and the phase 1 pharmacokinetic study for RADICAVA ORS.[2]

- Results from a phase 1 pharmacokinetic study in healthy subjects under fasted conditions showed equivalent plasma levels with RADICAVA ORS and RADICAVA[2]
- In the pivotal phase 3 clinical trial, patients on RADICAVA lost on average 2.49-fewer points on the ALSFRS-R from baseline indicating physical function declined slower over time vs placebo[2]

Q What studies were evaluated in the approval of RADICAVA ORS?

Seven clinical studies specific to RADICAVA ORS were conducted, in addition to the original set of clinical studies for RADICAVA.[2-10]

- The 7 studies examined the pharmacokinetics, bioequivalence, safety, tolerability, bioavailability, and alternative administration of RADICAVA ORS in healthy individuals and in patients with ALS[4-10]
  - One of these studies was a 6-month, open-label clinical trial evaluating the safety and tolerability of RADICAVA ORS in 185 patients with ALS[2]
- RADICAVA ORS efficacy is supported by data from a pivotal clinical trial for RADICAVA[2,11]

Q Can RADICAVA ORS be taken with riluzole?

- More than 90% of patients in the pivotal clinical trial for RADICAVA were on riluzole[11]
- 87% of patients in a safety trial for RADICAVA ORS were on riluzole[12]
- There are no known drug-drug interactions (DDIs) associated with RADICAVA ORS[2]

Consider RADICAVA ORS in addition to riluzole upon diagnosis.[1,11]

ALS=amyotrophic lateral sclerosis; ALSFRS-R=ALS Functional Rating Scale–Revised; IV=intravenous.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (≥10%) reported in RADICAVA® (edaravone)-treated patients and at least 2% more frequently than placebo were contusion (15% vs 9%), gait disturbance (13% vs 9%), and headache (10% vs 6%), respectively. In an open label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Mechanism of action

Q What is the mechanism of action of RADICAVA ORS®?

The exact mechanism of action of edaravone to treat ALS is unknown. It is believed, based on preclinical studies, to reduce oxidative stress.[2,4]

Safety profile and contraindications

Q What is the safety profile of RADICAVA ORS?

RADICAVA ORS has a demonstrated safety and tolerability profile which was shown in a 6-month, phase 3, open-label clinical trial in 185 patients with ALS, and offers a similar safety profile as the IV formulation.[2]

- In a clinical trial for RADICAVA® (edaravone), the most common adverse reactions (≥10%) were contusion, gait disturbance, and headache. Fatigue was observed in 7.6% of patients in the open-label study of RADICAVA ORS[2]
- RADICAVA and RADICAVA ORS have the same Contraindications and Warnings and Precautions. (See Important Safety Information on page 13)[2]

Q Does RADICAVA ORS have any drug interactions?

There are no known DDIs associated with RADICAVA ORS.[2]

- The pharmacokinetics of edaravone are not expected to be significantly affected by inhibitors of cytochrome P450 (CYP) enzymes, UGTs, or major transporters[2]

See Section 12.3 “Pharmacokinetics” in the full Prescribing Information for additional details.

UGT=uridine diphosphate glucuronosyltransferase.

IMPORTANT SAFETY INFORMATION

Pregnancy

Based on animal data, RADICAVA ORS may cause fetal harm.

To report suspected adverse reactions or product complaints, contact Tanabe Pharma America, Inc., at 1-888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Safety profile and contraindications (cont.)

Q Does RADICAVA ORS have any contraindications?

RADICAVA ORS is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients in this product. Hypersensitivity reactions and anaphylactic reactions have occurred.[2]

- Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA ORS, treat per standard of care, and monitor until the condition resolves[2]

Q Can patients take RADICAVA ORS if they are pregnant or breastfeeding?

Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with RADICAVA ORS, or if they intend to breastfeed or are breastfeeding.[2]

- There are no adequate data on the developmental risk associated with the use of RADICAVA ORS in pregnant women. Based on animal data, RADICAVA ORS may cause fetal harm[2]
- There are no data on the presence of edaravone in human milk, the effects on the breastfed infant, or the effects of the drug on milk production[2]

Q What was the discontinuation rate in the safety study of RADICAVA ORS?

There was a low rate of discontinuations due to adverse events.[12]

- Only 4 patients discontinued treatment in the first 2 months (4/185)
- 5.9% of patients (11/185) discontinued RADICAVA ORS due to AEs
- 1.1% of patients (2/185) discontinued RADICAVA ORS due to GI-related AEs, including diarrhea (0.5%) and dysphagia (0.5%)
- >1% of patients (4/185) discontinued for other reasons, including respiratory failure (1.1%) and muscular weakness (1.1%)

AE=adverse event; GI=gastrointestinal.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

RADICAVA ORS® (edaravone) is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Dosing and administration

Q How is RADICAVA ORS® administered?

RADICAVA ORS was designed with ALS patients in mind[2]:

- 5 mL dose administered in minutes, not hours
- Flexible administration options: orally or through PEG/NG tube using an oral syringe
- No infusion required
- The RADICAVA ORS bottle should be shaken for at least 30 seconds before each use
- RADICAVA ORS should be taken in the morning on an empty stomach after overnight fasting. Food should not be consumed for 1 hour after administration except water
- Portable—can be stored upright, at room temperature by the patient and dosed at or away from home[a]

These are not the full instructions for administration. See Section 2.3 "Preparation and Administration Information for RADICAVA ORS Oral Suspension" of the Prescribing Information to learn more.

Q What is the dosing schedule for RADICAVA ORS?

- For the initial treatment cycle, RADICAVA ORS is taken daily for 14 consecutive days followed by 14 consecutive drug-free days[2]
- For subsequent treatment cycles, RADICAVA ORS is taken for 10 out of 14 treatment days followed by 14 consecutive drug-free days[2]

Q Are there fasting requirements with RADICAVA ORS?

RADICAVA ORS should be taken on an empty stomach in the morning after overnight fasting. Patients should not consume any food or drink (except water) for 1 hour after administration.[2]

Food can affect the absorption of the medication. Patients should wait 8 hours after having high-fat meals (800-1000 calories, 50% fat), or 4 hours after low-fat meals (400-500 calories, 25% fat), or 2 hours after a caloric supplement (250 calories, eg, protein drink).[2]

[a]In the pharmacy, store RADICAVA ORS refrigerated between 2°C and 8°C (36°F–46°F) and protect from light. Do not freeze. Store upright. Patients should store RADICAVA ORS upright at room temperature between 20°C and 25°C (68°F–77°F) and protect from light. Discard 15 days after opening bottle or, if unopened, 30 days from date of shipment indicated on the carton pharmacy label.[2]
NG=nasogastric; PEG=percutaneous endoscopic gastrostomy.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions *(continued)*

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Dosing and administration (cont.)

Q What can my patients expect with their RADICAVA ORS® shipments?

View Instructions for Use.

Q What are the ingredients in RADICAVA ORS?

The active ingredient in RADICAVA ORS is edaravone.[2]

Inactive ingredients include L-cysteine hydrochloride hydrate, polyvinyl alcohol, simethicone emulsion, sodium bisulfite, sorbitol, and xanthan gum. Phosphoric acid and sodium hydroxide are added to adjust to pH 4.[2]

Q What does RADICAVA ORS taste like?

RADICAVA ORS has no flavoring added, but it does contain sorbitol, an ingredient with a mildly sweet taste.[2,13]

IMPORTANT SAFETY INFORMATION

Sulfite Allergic Reactions

RADICAVA ORS contains sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Dosing and administration (cont.)

Q With the discontinuation of RADICAVA® IV, can patients be switched to RADICAVA ORS?

Yes, if appropriate, patients treated with 60 mg of RADICAVA IV may be switched to 105 mg (5 mL) RADICAVA ORS using the same dosing frequency. Upon switching to RADICAVA ORS, patients should follow RADICAVA ORS dosing recommendations with regards to food consumption.[2]

See Section 2.4 "Switching from RADICAVA to RADICAVA ORS" of the Prescribing Information to learn more.

- See the "Treatment Landscape" section on page 12 to learn more about how RADICAVA ORS was designed with your patients in mind

Storage and handling

Q How is RADICAVA ORS stored?

Patients should store RADICAVA ORS upright at room temperature between 20°C and 25°C (68°F to 77°F). Protect from light. Discard 15 days after opening the bottle or, if unopened, 30 days from date of shipment indicated on the carton pharmacy label.[2]

Pharmacies should store RADICAVA ORS refrigerated between 2°C and 8°C (36°F to 46°F) and protect from light. Do not freeze. Store upright.[2]

Q How is RADICAVA ORS supplied?

RADICAVA ORS is supplied in a white-to-off-white oral suspension in a multidose, child-resistant 60 mL amber glass bottle. It is supplied as 2 configurations[2]:

- RADICAVA ORS Starter Kit (14-day treatment cycle), if initially prescribed, includes 2 inner cartons. Each carton contains 1 bottle of 735 mg/35 mL (105 mg/5 mL dose), 2 oral dosing syringes, and 1 bottle adapter
- RADICAVA ORS Maintenance Kit (10-day treatment cycle) includes 1 bottle of 1050 mg/50 mL (105 mg/5 mL dose) with 2 oral dosing syringes and 1 bottle adapter

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (≥10%) reported in RADICAVA® (edaravone)-treated patients and at least 2% more frequently than placebo were contusion (15% vs 9%), gait disturbance (13% vs 9%), and headache (10% vs 6%), respectively. In an open label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Accessibility

Q What will the out-of-pocket cost be for my patients?

RADICAVA ORS® has formulary access with 85% of all payers (including the Veterans Affairs National Formulary) and is covered by 96% of all commercial plans.[12,14,a]

93% of eligible commercial patients who utilized the Out-of-Pocket Assistance Program paid $0 per prescription.[12,b,c]

With medical exceptions, 100% of all Medicare plans cover RADICAVA ORS[12,a]

- 60.39% Covered with medical exception
- 36.30% Covered (PA/ST)
- 3.31% Covered

This information is provided for educational purposes only. Tanabe Pharma America does not guarantee coverage or reimbursement. Formulary status subject to change.

[a]Data on file. Tanabe Pharma America, Inc. As of February 2025.
[b]For eligible patients with commercial insurance. Annual maximum benefit per patient. Additional terms and conditions apply. See full Eligibility Requirements and Terms & Conditions.
[c]Based on claims prescriptions dispensed submitted to the Out-of-Pocket Assistance Program from January 1, 2024 to October 31, 2024.
PA=prior authorization; ST=step therapy.

IMPORTANT SAFETY INFORMATION

Pregnancy

Based on animal data, RADICAVA ORS may cause fetal harm.

To report suspected adverse reactions or product complaints, contact Tanabe Pharma America, Inc., at 1-888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Accessibility (cont.)

Q How can I determine if RADICAVA ORS is covered by insurance?

RADICAVA ORS has formulary coverage among major health insurance carriers including ESI, CVS, Express Scripts, Optum, Prime Therapeutics, and Veterans Affairs (VA).

- To determine if RADICAVA ORS is covered by insurance, please follow the steps below:
  1. Submit a completed Benefit Investigation and Enrollment Form (BIF) with the patient's signature
  2. After submitting a BIF, call the Insurance & Access Specialists at ***JourneyMate Support Program***™ to determine insurance coverage (1-855-457-6968). See below for more information

Once you have prescribed RADICAVA ORS and submitted a BIF to check how your patient's health insurance covers RADICAVA ORS, an Insurance & Access Specialist will reach out to the patient to help them understand the insurance process.

An Insurance & Access Specialist will:

- Help investigate a patient's health insurance coverage and health plan benefits, as well as the RADICAVA ORS financial support options which may be available to patients if they meet all eligibility criteria
- Help patients understand how to access RADICAVA ORS
- They are also available throughout the patient's treatment journey to help answer insurance and access-related questions

Visit radicavaorshcp.com/journeymate to learn more about the *JourneyMate Support Program*™.

A **JourneyMate Support Program**™ *Insurance & Access Specialist is provided by UBC on behalf of Tanabe Pharma America, Inc. (TPA). A* **JourneyMate Support Program**™ *Insurance & Access Specialist may provide information obtained from outside sources about a patient's insurance coverage, financial support options, and whether treatment is covered by their health plan. This information does not require a patient or their doctor to use any TPA product. Because the information provided comes from outside sources, a* **JourneyMate Support Program**™ *Insurance & Access Specialist cannot guarantee the information will be accurate or complete.*

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

RADICAVA ORS® (edaravone) is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Patient support

Q How are the patients who are Veterans being supported?

Veterans with ALS may be eligible for treatment with RADICAVA ORS® and other benefits from VA.[15]

- RADICAVA ORS is on the VA National Formulary[14]
- Currently, over 600 Veterans are on RADICAVA ORS[12]
- Veterans can check with their local VHA enrollment center or military treatment facility DEERS office for more information on nonmedical benefits
- VA and the VHA recognize ALS as a service-connected disease and offer[16]:
  - Medical and financial support to those with at least 90 continuous days of military service[15,17]
  - Resources, education, and support for care partners of Veterans[18]
  - Some benefits to a Veteran's spouse or children, even if the Veteran has passed away due to ALS[15]

Q Is there patient support available?

The ***JourneyMate Support Program***™ helps to give patients and their care partners understanding, answers, and resources to supplement what their doctor provides. Experienced program team members are trained to address their educational needs and provide them with personalized answers and resources for living with ALS.

- **JourneyMate Resource Specialist:** A go-to resource in the ***JourneyMate Support Program***™ for general information about ALS and RADICAVA ORS
- **Insurance & Access Specialist:** This specialist can help answer questions about insurance coverage, financial support options, specialty pharmacy options, and the steps to accessing their RADICAVA ORS prescription
- **ALS Clinical Educator:** Once you've prescribed RADICAVA ORS, an ALS Clinical Educator can provide patients and their care partners with personalized education about RADICAVA ORS and resources to support their treatment

The ***JourneyMate Support Program***™ *offers educational support and resources for patients who are considering or have already been prescribed a Tanabe Pharma America, Inc. (TPA) product. An ALS Clinical Educator is an educational resource for patients who have been prescribed an TPA product. An ALS Clinical Educator is provided by TPA and Momentum Life Sciences and is not affiliated with or provided by a doctor. An ALS Clinical Educator does not provide medical advice. The program does not provide medical advice and does not take the place of a patient's doctor. All questions about a condition, diagnosis, or treatment should be referred to the patient's doctor. If a patient has a medical emergency, they should call 911. Adverse events or product complaints should be reported by calling 1-888-292-0058.*

DEERS=Defense Enrollment Eligibility Reporting System; VA=Veterans Affairs; VHA=Veterans Health Administration.

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions *(continued)*

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

Treatment landscape

Q What evidence and clinical history were used to support the FDA approval of RADICAVA ORS®?

The FDA based their approval on results from multiple studies, including the phase 1 pharmacokinetic study demonstrating that RADICAVA ORS has equivalent plasma levels to RADICAVA® (edaravone).[2]

- Efficacy was demonstrated in the pivotal phase 3 trial that showed RADICAVA slowed the loss of physical function by 33% vs placebo, measured over 24 weeks by the ALSFRS-R[11]
- 8 studies of RADICAVA ORS have been completed, including 7 phase 1 clinical pharmacology studies examining the pharmacokinetics, safety, DDIs, dosing, bioavailability, and bioequivalence of oral edaravone in healthy individuals and ALS patients, with and without a PEG/NG tube[2,4-10]
- The safety profile of RADICAVA ORS was demonstrated in a 6-month, open-label clinical trial in 185 patients[2]
  - The most common adverse reactions (≥10%) reported in RADICAVA-treated patients and at least 2% more frequently than placebo were contusion (15% vs 9%), gait disturbance (13% vs 9%), and headache (10% vs 6%), respectively. In an open-label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS[2]

Q Why was an oral formulation of RADICAVA created?

RADICAVA ORS was designed for patients with ALS in mind.

- In 2024, the FDA recognized RADICAVA ORS as a major contribution to patient care, due to its oral route of administration which is less burdensome for patients than IV administration[19]

FDA=Food and Drug Administration.

IMPORTANT SAFETY INFORMATION

Sulfite Allergic Reactions

RADICAVA ORS contains sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Please see the additional Important Safety Information on page 13 and the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

INDICATION

RADICAVA ORS® (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

RADICAVA ORS® (edaravone) is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred.

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Sulfite Allergic Reactions

RADICAVA ORS contains sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Adverse Reactions

The most common adverse reactions (≥10%) reported in RADICAVA® (edaravone)-treated patients and at least 2% more frequently than placebo were contusion (15% vs 9%), gait disturbance (13% vs 9%), and headache (10% vs 6%), respectively. In an open label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS.

Pregnancy

Based on animal data, RADICAVA ORS may cause fetal harm.

To report suspected adverse reactions or product complaints, contact Tanabe Pharma America, Inc., at 1-888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information, also available at www.radicavaors.com.

Radicava ORS®
(edaravone) Oral Suspension
105mg/5mL

References: 1. Leigh PN, Swash M, Iwasaki Y, et al. Amyotrophic lateral sclerosis: a consensus viewpoint on designing and implementing a clinical trial. *Amyotroph Lateral Scler Other Motor Neuron Disord*. 2004;5(2):84-98. **2.** RADICAVA and RADICAVA ORS Prescribing Information. Jersey City, NJ: Tanabe Pharma America, Inc.; 2025. **3.** Takei K, Watanabe K, Yuki S, et al. Edaravone and its clinical development for amyotrophic lateral sclerosis. *Amyotroph Lateral Scler Frontotemporal Degener*. 2017;18(suppl 1):5-10. **4.** Shimizu H, Nishimura Y, Shiide Y, et al. Bioequivalence study of oralsuspension and intravenous formulation of edaravone in healthy adult subjects. *Clin Pharmacol Drug Dev*. 2021;10(10):1188-1197. **5.** ClinicalTrials.gov. Study of oral edaravone in healthy adult males. Accessed September 25, 2024. https://clinicaltrials.gov/study/ NCT04481750 **6.** ClinicalTrials.gov. Clinical pharmacology study of oral edaravone in patients with amyotrophic lateral sclerosis. Accessed September 25, 2024. https://clinicaltrials.gov/study/NCT04176224 **7.** ClinicalTrials.gov. Clinical pharmacology study of oral edaravone in healthy adult males (drug interaction study and preliminary regimen-finding study). Accessed September 25, 2024. https://clinicaltrials.gov/study/NCT04481789 **8.** ClinicalTrials.gov. Clinical pharmacology study of oral edaravone in amyotrophic lateral sclerosis patients with gastrostomy. Accessed September 25, 2024. https://clinicaltrials.gov/study/NCT04254913 **9.** ClinicalTrials.gov. Safety study of oral edaravone administered in subjects with ALS. Accessed September 25, 2024. https://clinicaltrials.gov/study/NCT04165824 **10.** ClinicalTrials.gov. Comparative bioavailability study of oral edaravone administered orally and via a nasogastric tube. Accessed September 25, 2024. https://clinicaltrials.gov/study/NCT04776135 **11.** Writing Group; Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol*. 2017;16(7):505-512. **12.** Data on file. Tanabe Pharma America, Inc. **13.** National Center for Biotechnology Information. PubChem compound summary for CID 5780, sorbitol. Accessed January 10, 2025. https://pubchem.ncbi.nlm.nih.gov/compound/Sorbitol#section=Taste **14.** US Department of Veterans Affairs. Pharmacy benefits management services. Search: edaravone. Accessed September 20, 2024. https://www.pbm.va.gov/apps/VANationalFormulary **15.** US Department of Veterans Affairs. *Federal Benefits for Veterans, Dependents, Survivors, and Caregivers*. 2023; VA Pamphlet 80-19-03. Accessed September 20, 2024. https://www.va.gov/opa/publications/benefits_book/2023_Federal_Benefits_for_Veterans_Dependents_and_Survivors.pdf **16.** US Department of Veterans Affairs. VA makes specially adaptive housing grant eligibility automatic for veterans and servicemembers living with ALS [news release]. Published March 19, 2014. Accessed September 20, 2024. https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2530 **17.** US Department of Veterans Affairs. ALS awareness month. Accessed September 20, 2024. https://www.va.gov/marion-health-care/stories/als-awareness-month **18.** US Department of Veterans Affairs. VA caregiver support program. Accessed September 25, 2024. https://www.caregiver.va.gov/Care_Caregivers.asp **19.** US Food and Drug Administration. Clinical superiority findings. Accessed January 10, 2025. https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/clinical-superiority-findings

Tanabe Pharma America