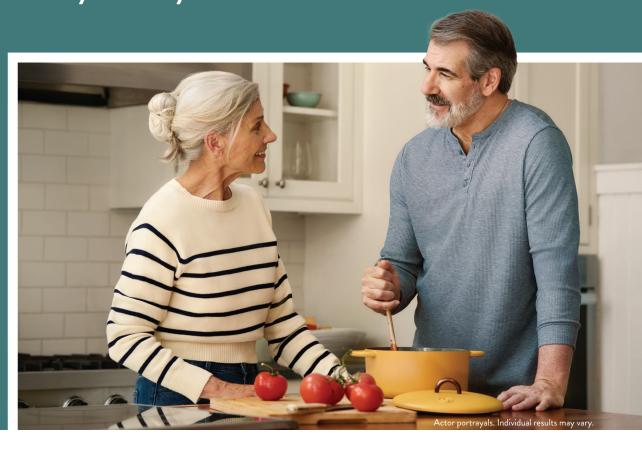
# YOUR ROLE AS AN ALS CARE PARTNER

Support and resources for both you and your loved one



### **INDICATION**

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

### **IMPORTANT SAFETY INFORMATION**

**Do not receive RADICAVA ORS® (edaravone) if you** are allergic to edaravone or any of the ingredients in RADICAVA ORS.

Before you take RADICAVA ORS, tell your healthcare provider about all of your medical conditions, including if you:

- · have asthma.
- are allergic to other medicines.

Please see the full <u>Prescribing Information</u> and <u>Patient Information</u>, also available at www.radicavaors.com.



### Navigating ALS Together

### In the following pages, you'll find:

Information about RADICAVA ORS, such as product benefits, dosing and administration, insurance coverage, and our patient support program.

Guidance to help you support your loved one along their journey with ALS.

Information and resources to help care for yourself as you care for them.

### What does being an ALS care partner mean?

As a care partner to someone living with ALS, your role is invaluable—providing both physical care and emotional strength to your loved one on every step of their journey.

While the duties of a care partner are unique to each situation, they often include personal care, assistance with mobility, and working with your loved one's care team to find the best possible resources to help manage their condition. Some examples of what you might expect are:



### Providing physical and emotional support

- Helping with physical tasks like cooking or getting dressed
- Encouraging your loved one to express how they are feeling



### Taking part in their medical needs

- Being an active participant in treatment decisions
- Scheduling and attending appointments
- Administering medication and monitoring for side effects



### Managing logistics

- Coordinating insurance coverage
- Picking up prescriptions
- · Doing or delegating household tasks

Remember, this is a team effort between you, your loved one, and your support network. Clear and open communication is a key part of making decisions about day-to-day needs together.



### How RADICAVA ORS® May Help

### How ALS progression is measured

Your loved one's doctor may use a tool called the ALS Functional Rating Scale–Revised (ALSFRS-R) to help keep track of the body's physical progression. The scale is made up of 12 activities across 4 categories:



Bulbar (eg, speech)



Fine Motor (eg, cutting food)



Gross Motor (eg, walking)

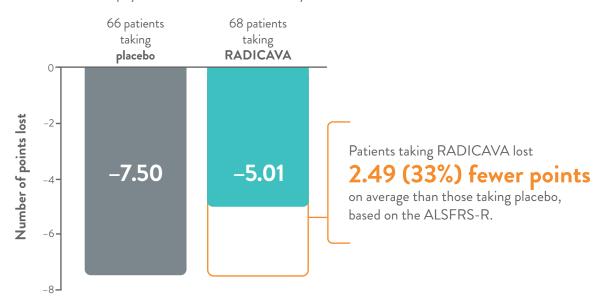


Respiratory (eg, breathing)

Each activity is rated on a scale from 0 (unable to perform) to 4 (normal function), adding up to a total of 48 points. **Higher scores mean more physical function.** 

### RADICAVA ORS®: proven to help slow the loss of physical function

RADICAVA ORS is an oral form of RADICAVA® (edaravone). In the clinical study, RADICAVA slowed the loss of physical function, as measured by the ALSFRS-R.



#### IMPORTANT SAFETY INFORMATION

Before you take RADICAVA ORS, tell your healthcare provider about all of your medical conditions, including if you: (cont.)

- are pregnant or plan to become pregnant. It is not known if RADICAVA ORS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if RADICAVA ORS passes into your breastmilk. You and your healthcare provider should decide if you will receive RADICAVA ORS or breastfeed.

Radicava ORS (edaravone) Oral Suspension (issue) Similar (issue) (issue) Similar (issue) (issu

### RADICAVA ORS® Was Generally Well Tolerated

### Side effect profile



The safety profile of RADICAVA (edaravone) was evaluated in multiple placebo-controlled studies in 184 patients with ALS



RADICAVA ORS was generally well tolerated in a 6-month clinical study of 185 patients with ALS

Common side effects reported include bruising (contusion), problems walking (gait disturbance), headache, and fatigue. These are not all the possible side effects of RADICAVA ORS.

## Fewer than 6% of patients (11/185) discontinued RADICAVA ORS because of side effects in a 6-month safety study of patients with ALS

 Approximately 1% (2/185) discontinued RADICAVA ORS due to gastrointestinal side effects (diarrhea and trouble swallowing)

Be sure to tell your doctor if you are allergic to other medications and share all of the medications you are taking.

The safety profiles of RADICAVA and RADICAVA ORS were established in 500+ patients with ALS in multiple clinical studies.

### **IMPORTANT SAFETY INFORMATION**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### What are the possible side effects of RADICAVA ORS?

RADICAVA ORS may cause serious side effects, including hypersensitivity (allergic) reactions and sulfite allergic reactions.

• Hypersensitivity reactions have happened in people taking RADICAVA ORS and can happen after your medicine has been taken.

Radicava ORS (edaravone) Oral Suspension (los mg/sm.

## How RADICAVA ORS® Can Fit Into Both of Your Routines

### RADICAVA ORS is an oral treatment



Can be taken orally (by mouth) or via feeding tube



5 mL oral dose may take only a few minutes to administer on treatment days<sup>a</sup>



Requires shaking but does not require water or additional mixing steps



Can be stored at room temperature so you can take it at home or on the gob

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.



"When it's time to take RADICAVA ORS, my husband will open the bottle for me and leave it on my bedside table so it's ready first thing in the morning and it's easy for me to take."

Stephanie, living with ALS

RADICAVA ORS is recognized by the FDA as a major contribution to patient care because it can be taken orally (by mouth), which is a less burdensome option than IV administration.

<sup>a</sup>Use the provided 5 mL syringe that comes with the product. Do not use a household teaspoon to measure the medication. <sup>b</sup>Store RADICAVA ORS upright at room temperature between 68°F and 77°F. Protect from light.

#### IMPORTANT SAFETY INFORMATION

What are the possible side effects of RADICAVA ORS? (cont.)

- RADICAVA ORS contains sodium bisulfite, a sulfite that may cause a type of allergic reaction that
  can be serious and life-threatening. Sodium bisulfite can also cause less severe asthma episodes in
  certain people. Sulfite sensitivity can happen more often in people who have asthma than in people
  who do not have asthma.
- Tell your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms: hives; swelling of the lips, tongue, or face; fainting; breathing problems; wheezing; trouble swallowing; dizziness; itching; or an asthma attack (in people with asthma).

Radicava ORS (edaravone) OSI Suspension

### RADICAVA ORS®

### Dosing Schedule and Guidance

### Mark the calendar to stay on track with treatment

Starter treatment cycle (first cycle only):



 RADICAVA ORS is taken once daily for 14 days, followed by 14 days off in a row Maintenance treatment cycle (all other cycles):



- RADICAVA ORS is taken on 10 of 14 days, followed by 14 days off in a row each month
- Taking RADICAVA ORS daily can occur on any 10 days in the 14-day treatment period

### Fasting guidance for RADICAVA ORS

There are several considerations for your loved one before taking RADICAVA ORS, which should be taken in the morning on an empty stomach after overnight fasting. No food or drink should be consumed (except water) for 1 hour after administration. Your loved one's doctor can help answer dosing questions or concerns.

	Fasting times before and after administration	
Type of meal/supplement consumed	Before	After
High-fat meal (800-1000 calories, 50% fat)	8 hours	1 hour
Low-fat meal (400-500 calories, 25% fat)	4 hours	1 hour
Caloric supplement (250 calories, eg, protein drink)	2 hours	1 hour

Read the Instructions for Use before taking RADICAVA ORS.

#### **IMPORTANT SAFETY INFORMATION**

Your healthcare provider will monitor you during treatment to watch for signs and symptoms of all the serious side effects and allergic reactions.

Common side effects reported include bruising (contusion), problems walking (gait disturbance), headache and fatigue. These are not all the possible side effects of RADICAVA ORS.

Please see the full <u>Prescribing Information</u> and <u>Patient Information</u>, also available at <u>www.radicavaors.com</u>.



## Preparing and Administering the Medication

As your loved one continues along their ALS journey, they may start to need assistance with taking their medication. Be sure to talk about which administration steps they may need support with. It can be a learning curve at first, so developing a routine can help.

Use the provided 5 mL syringe that comes with the product. Do not use a household teaspoon to measure your medication.



Some steps for administering RADICAVA ORS® require strength, fine motor skills, and dexterity that your loved one may need assistance with:

- Twisting off/on the bottle cap
- Inserting the bottle adapter firmly on the bottle
- Shaking the bottle vigorously
- · Using the oral syringe
- Inserting the oral syringe into the catheter (for those who require a feeding tube)



Please read the Instructions For Use prior to helping your loved one prepare and administer their medication.

Seek immediate medical care if you experience signs or symptoms of an allergic reaction.



Visit radicavaors.com/dosingadminguide to download the Dosing and Administration Guide for more information.

#### IMPORTANT SAFETY INFORMATION

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or Tanabe Pharma America, Inc. at 1-888-292-0058.

Please see the full <u>Prescribing Information</u> and <u>Patient Information</u>, also available at www.radicavaors.com.



### Taking Care of Your Loved One

### Technology and equipment to help along the way

In addition to medication, advances in assistive technology and adaptive equipment can help people with ALS perform daily functions, maintain independence longer, and live more comfortable lives.

Some of these include:



### Adaptive clothing

Clothing designed for people who have difficulty dressing. These make daily activities, such as dressing and using the bathroom, easier.



### Portable showers

Portable showers can be attached to any faucet, have waterproof sides, allow enough room for a wheelchair to roll in, and have a pump to allow water to flow out into the sink. These can be used if a person has difficulty accessing the bathroom.



#### **Bidets**

If a person with ALS loses hand function, bidets offer a level of independence and can be added to any existing toilet.



### **Emergency alert devices**

These can give care partners peace of mind in a scenario where a person with ALS falls and is unable to get up. In this case, they simply push a button on a bracelet, pendant, or switch to alert an operator, who then connects them with support.



#### Cameras

Especially useful for care partners who work remotely, cameras provide a means to monitor a person with ALS throughout the day.



### Home automation systems

These can allow people with ALS with limited or no hand function to remotely open doors, adjust thermostats, or turn on a TV and other electrical devices.

### Taking Care of YOU

As a care partner, you play an invaluable role in supporting your loved one with ALS. But let's not forget about you and your own needs, including taking care of your physical and emotional health.

Here are a few suggestions:



### Seek emotional health support

Being a care partner can affect your mental and emotional health.

- Mental health providers are trained to assist people in many life situations, including those who are caring for a person with a progressive disease
- · Talk to your doctor if you're having concerns



### Ask for help

Reach out to family and friends when you need a hand and be open to accepting help when it's offered.

- As ALS progresses, consider leaning on others for support so you can take the time you need to recharge
- · Look into local, state, and federal programs that may provide support and assistance



### Be kind to yourself

Feelings of guilt and anger are normal.

- · Don't let them keep you from recognizing the amazing job you're doing
- Recognize that caring for yourself can help you provide the best possible care for your loved one



### Manage your stress

Set expectations with your loved one, family, and friends.

- · Communicate your feelings and needs
- · Take part in activities that reduce stress
- · Seek counseling, as it may also be beneficial



### Consider your personal needs

Continuing to do the things that are important and enjoyable to you is not selfish. Doing so may help improve your ability to care for your loved one.

· Build in regular breaks from care partnering and make them a priority



### Talk to other care partners

Connect with others who are caring for someone with a progressive illness who can lend an understanding ear. Other care partners can:

- Be a source of great support
- Offer advice
- Share solutions to common problems

### Setting Aside Time for Self Care

Being a care partner can be fulfilling. It can also consume a great deal of your physical, mental, and emotional energy. Burnout can make it difficult to be the partner you want to be, and it may also take a toll on your health.

Look out for these signs of burnout:	What is respite care?	
Social withdrawal	Respite care is simply a moment or period of rest or relief. It is meant to give you a	
• Inability to sleep	break from your daily care responsibilities.  It's important to have a conversation with your loved one about taking time for yourself, before you need it.	
• Exhaustion		
<ul> <li>Irritability</li> </ul>		
<ul> <li>Inability to relax or concentrate</li> </ul>	There are different ways to give you the chance to have respite care. These include:	
<ul> <li>Forgetfulness</li> </ul>	<ul> <li>In-home substitute care from a trained professional</li> </ul>	
Depression and anxiety	<ul> <li>Short-term stay for your loved one at a facility or residence that has trained</li> </ul>	
• Lack of appetite	healthcare staff onsite	
	<ul> <li>Asking your family and friends to help out</li> </ul>	



- "I found that having a meeting, getting people together and asking them how they wanted to help, was wonderful. Give them a list of the options to choose from. People with skills just really can make a huge difference."
- Jodi, care partner and advocate

### **ALS Websites and Online Communities**

#### **ALS** Association

### als.org

Works to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

#### **ALS Network**

### alsnetwork.org

Partners with the ALS community to help drive the discovery of prevention strategies, treatments, and cures for ALS; provides access to quality care and connection, and promotes initiatives to improve health outcomes.

### **ALS United Mid-Atlantic**

### alsmidatlantic.org

Empowers the ALS community through a collaborative approach to fostering bold research initiatives, advancing national and state advocacy, and providing comprehensive care and support to individuals and families affected by ALS.

### CaringInfo

### caringinfo.org

Free resources and information, provided by the National Hospice and Palliative Care Organization, to help people make informed decisions about end-of-life care and services before a crisis.

### Compassionate Care ALS

### ccals.org

A nonprofit organization dedicated to supporting people with ALS and their families and communities as they navigate the physical and emotional demands of the disease. Includes educational workshops, guidance, and awareness.

### Her ALS Story heralsstory.org

A network for women under 35, offering connection, support, and sharing personal stories and hacks for life with ALS.

### Hope Loves Company hopelovescompany.org

A nonprofit that provides support for children who currently have or had loved ones living with ALS. Dedicated to giving children and young adult caregivers a community to lean on as well as tools and resources.

Tanabe Pharma America, Inc. is not affiliated with and does not control or endorse the third-party content on the websites listed. The information and advice provided are general in nature and are not intended to be a substitute for professional medical advice, diagnosis, or treatment. You are strongly encouraged to seek the advice of your doctor or other qualified healthcare provider with any questions regarding a medical condition.

### ALS Websites and Online Communities (cont.)

#### I Am ALS

### <u>iamals.org</u>

Works to build a movement to cure ALS through collaboration, resources, engagement, awareness, and funding.

### International Alliance of ALS/MND Associations als-mnd.org

Online group of more than 50 patient support and advocacy groups worldwide that have joined together to provide support and the exchange of information between the associations.

### Live Like Lou livelikelou.org

A foundation that honors Lou Gehrig's legacy by supporting families affected by ALS and funding ALS research.

### Muscular Dystrophy Association mda.org

The #1 voluntary health organization in the United States for people living with muscular dystrophy, ALS, and related neuromuscular diseases.

### National Association for Home Care & Hospice nahc.org

Largest professional association representing the interests of chronically ill, disabled, and dying Americans of all ages and the care partners who provide them with in-home health and hospice services.

### Team Gleason teamgleason.org

A nonprofit organization with the mission to improve life for people living with ALS by delivering innovative technology and equipment, as well as providing and empowering an improved life experience.

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### RADICAVA ORS® Cost and Coverage



RADICAVA ORS is widely available, with coverage through all Medicare plans (with medical exceptions) and almost all commercial insurance plans.



With the RADICAVA ORS **Out-of-Pocket Assistance program**, prescription costs can be reduced or even eliminated for those who are eligible and have commercial insurance. Terms and restrictions apply. Visit <u>radicavaors.com</u> for more details.



Contact a JourneyMate Support Program™ Insurance & Access Specialist for patient-focused answers and resources.

Insurance & Access Specialist 1-844-772-4548 Monday through Friday, 8 AM to 8 PM ET

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.

#### **INDICATION**

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- have asthma.
- · are allergic to other medicines.
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- are breastfeeding or plan to breastfeed. It is not known if RADICAVA ORS passes into your breastmilk. You and your healthcare provider should decide if you will receive RADICAVA ORS or breastfeed.

Radicava OR (edaravone) 105 mg/sml



Dedicated Team. Patient-Focused Approach.

No matter where you are in your ALS journey—from diagnosis to treatment—the **JourneyMate Support Program**<sup>TM</sup> gives you the understanding, answers, and resources to help you move forward. Experienced program team members are trained to address your educational needs and provide you with personalized answers and resources for living with ALS. This program is here to supplement the resources that your doctor provides.



### Resource Specialist

A go-to resource in the *JourneyMate Support Program*™ for general information about ALS and RADICAVA ORS® for people with ALS and their care partners.



#### **Insurance & Access Specialist**

This specialist can help answer questions people with ALS and their care partners have about financial support options and help them understand how to access RADICAVA ORS medication.



#### **ALS Clinical Educator**

Once you're prescribed RADICAVA ORS, an ALS Clinical Educator can provide personalized education to you and your family about RADICAVA ORS and will also provide resources to support your treatment.

To learn more, call 1-855-457-6968 between 9 AM and 9 PM ET, Monday through Friday, or visit <u>radicavaors.com</u>.

The JourneyMate Support Program<sup>TM</sup> 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.

#### **IMPORTANT SAFETY INFORMATION**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### What are the possible side effects of RADICAVA ORS?

RADICAVA ORS may cause serious side effects, including hypersensitivity (allergic) reactions and sulfite allergic reactions.

• Hypersensitivity reactions have happened in people taking RADICAVA ORS and can happen after your medicine has been taken.

Radicava ORS) (edaravone) Oral Suspension (bosmg/sml

### Resources for You

### Helpful tools for managing life with ALS and starting treatment with RADICAVA ORS®

### **Download** the RADICAVA ORS Patient Brochure

Features more detailed information on RADICAVA ORS including clinical history, the safety profile, and access information.



### <u>Download</u> the RADICAVA ORS Dosing and Administration Guide

Learn more about the dosing schedule for RADICAVA ORS and how you or your loved one can administer it.



### Watch recorded live webinars

Hear from experts and members of the ALS community about adjusting to life with ALS, finding support, and starting treatment with RADICAVA ORS.



For more helpful rescources visit radicava.com/patient/downloads.

#### IMPORTANT SAFETY INFORMATION

What are the possible side effects of RADICAVA ORS? (cont.)

- RADICAVA ORS contains sodium bisulfite, a sulfite that may cause a type of allergic reaction that can be serious and life-threatening. Sodium bisulfite can also cause less severe asthma episodes in certain people. Sulfite sensitivity can happen more often in people who have asthma than in people who do not have asthma.
- Tell your healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms: hives; swelling of the lips, tongue, or face; fainting; breathing problems; wheezing; trouble swallowing; dizziness; itching; or an asthma attack (in people with asthma).

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Common side effects reported include bruising (contusion), problems walking (gait disturbance), headache and fatigue. These are not all the possible side effects of RADICAVA ORS.







Find support and resources for your loved one along the ALS journey



**Know that your own health and self-care** is just as important as your loved one's, and taking care of yourself allows you to be the care partner you want to be

Visit radicavaors.com to learn more about RADICAVA ORS® and the treatment support that's available to you.

#### IMPORTANT SAFETY INFORMATION

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or Tanabe Pharma America, Inc. at 1-888-292-0058.

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