

RADICAVA® (edaravone) helps slow the loss of physical function in patients with amyotrophic lateral sclerosis (ALS).

# FOR YOUR MOMENTS BIG AND SMALL

WHY  
RADICAVA ORS®?



Actor portrayals.

RADICAVA ORS® (edaravone) can fit your life's routines with a **5 mL oral dose** of a proven treatment.

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

## INDICATION

RADICAVA (edaravone) and RADICAVA ORS (edaravone) are indicated for the treatment of amyotrophic lateral sclerosis (ALS).

## IMPORTANT SAFETY INFORMATION

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

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

- have asthma.
- are allergic to other medicines.

**Please see full Important Safety Information on page 15 and full Prescribing Information and Patient Information.**

# RADICAVA ORS® (edaravone): An Oral Formulation of a Proven Treatment

ALS can progress rapidly. Beginning treatment with RADICAVA ORS® can be an important step to managing your ALS.



*“When I talked with my neurologist about RADICAVA® (edaravone), we went over the potential side effects, and we both agreed that I should begin treatment. It was very important for me to start RADICAVA® as soon as possible since it’s shown to slow the loss of physical function.”*

— Juan, living with ALS

## IMPORTANT SAFETY INFORMATION (continued)

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

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

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

Edaravone, the active ingredient of RADICAVA ORS®, has been shown to slow the loss of physical function on the ALSFRS-R by 33% (approximately one-third) vs placebo at 24 weeks.

### Experience with edaravone

Studied for <b>over a decade</b> in research and development	RADICAVA ORS® has been evaluated in <b>7+ medical studies</b>
<b>Over 10,200</b> people with ALS have chosen to treat with RADICAVA ORS® or RADICAVA® <sup>a</sup>	Prescribed by <b>2000+</b> healthcare providers <sup>a</sup>

### Designed with you in mind

- 5 mL (teaspoon size) dose taken by mouth using the oral syringe that comes with the medication or via feeding tube<sup>b,c</sup>
- May take only a few minutes to administer on treatment days
- No water or additional mixing steps needed (shaking required)



<sup>a</sup>Based on RADICAVA ORS® and RADICAVA® prescriptions submitted in the US as of **January 2023**. Not independently verified.

<sup>b</sup>The initial treatment cycle starts with daily dosing of RADICAVA ORS® for 14 days followed by a 14-day drug-free period. Subsequent treatment cycles include daily dosing for 10 out of 14 days followed by a 14-day drug-free period.

<sup>c</sup>Use the provided 5 mL syringe that comes with the product. Do not use a household teaspoon to measure your medication. ALSFRS-R=ALS Functional Rating Scale–Revised.





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## Monitoring Progression

ALS is a neurological disease that progresses at different rates for different people. To help assess your physical function over time, your doctor may use a functional rating scale, called the ALSFRS-R, for people with ALS. The ALSFRS-R measures how you are doing now and will help track disease progression in the future.

### The ALSFRS-R consists of 12 questions in 4 categories:

	<b>Bulbar</b>	• Speech	• Salivation	• Swallowing
	<b>Fine Motor</b>	• Handwriting	• Cutting food	• Dressing and hygiene
	<b>Gross Motor</b>	• Turning in bed	• Walking	• Climbing stairs
	<b>Respiratory</b>	• Difficulty breathing or shortness of breath (dyspnea)	• Trouble breathing when lying down (orthopnea)	• Respiratory insufficiency

### IMPORTANT SAFETY INFORMATION *(continued)*

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

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

- Hypersensitivity reactions have happened in people receiving RADICAVA or taking RADICAVA ORS and can happen after your medicine has been given.
- RADICAVA and RADICAVA ORS contain 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).

On the ALSFRS-R, the higher the score, the greater the physical function.



### Losing or keeping a single point on the ALSFRS-R may have a significant impact.

The average rate of ALSFRS-R decline is 1.02 points/month (PRO-ACT database).

**1 point of functional loss in the ability to swallow** could mean going from being able to eat enough on your own to needing supplemental tube feeding.

**1 point of functional loss in the hands** may mean going from being able to feed yourself without assistance to needing help.

**A 1-point loss in the legs** could mean going from being able to walk with some assistance (for example, using a cane) to not being able to walk.

**A 1-point loss in breathing ability** could mean going from breathing on your own to occasionally needing to use a ventilator (or machine) to help with breathing.

To date, there are no treatments that can stop or reverse ALS progression, but there are medications available that may help slow the loss of physical function.

The sooner you start treatment, the sooner you may begin slowing the loss of physical function.

To see how the ALSFRS-R works and the impact of losing or keeping points, visit [RadicavaORS.com](https://www.RadicavaORS.com).

PRO-ACT=Pooled Resource Open-Access ALS Clinical Trials.

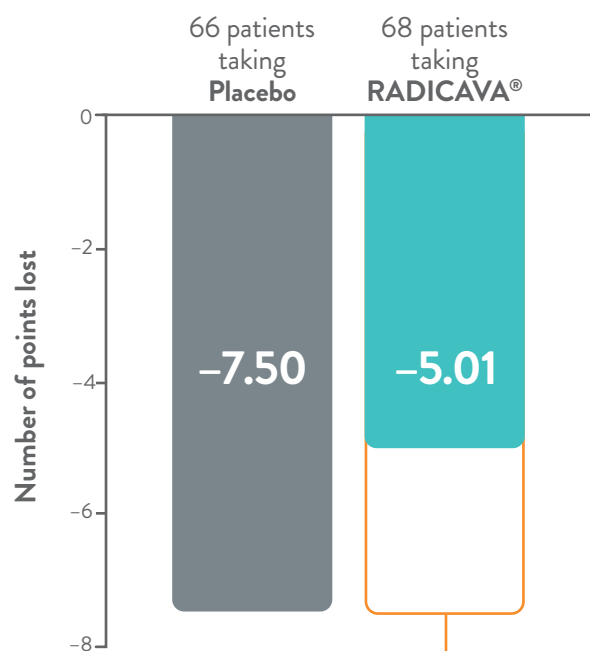
Please see full Important Safety Information on page 15 and full Prescribing Information and Patient Information.



# How RADICAVA ORS® (edaravone) May Help

RADICAVA ORS® is an oral form of edaravone.

RADICAVA® (edaravone) slowed the loss of physical function vs placebo at 24 weeks.



**2.49** fewer points lost on the ALSFRS-R with RADICAVA®

This means a **33%** less decline in physical function for patients on RADICAVA® vs those on placebo.

In the clinical study, RADICAVA® slowed the loss of physical function as measured by the ALSFRS-R. At 24 weeks (about 6 months), patients who did not receive RADICAVA® declined more rapidly in physical function, having lost an average of 2.49 points more than those who received RADICAVA®.

Individual results may vary.

## IMPORTANT SAFETY INFORMATION (continued)

### What are the possible side effects of RADICAVA and RADICAVA ORS? (continued)

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

The most common side effects include bruising (contusion), problems walking (gait disturbance), and headache.

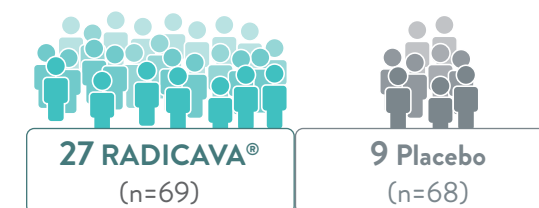
These are not all the possible side effects of RADICAVA or RADICAVA ORS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058.

On the ALSFRS-R, the fewer points lost, the greater the physical function.

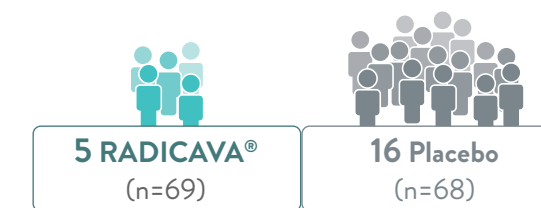


## Patients on RADICAVA® lost fewer points on the ALSFRS-R at 6 months.

**3X** as many patients given RADICAVA® lost 2 or less points (39.1% RADICAVA® vs 13.2% placebo)



**3X** as many patients given placebo lost 11 or more points (23.5% placebo vs 7.2% RADICAVA®)



A similar number of patients in both treatment arms lost 3 to 10 points (37/69 with RADICAVA® and 43/68 with placebo).

Over 90% of patients in each group were also being treated with riluzole.

“When it came to RADICAVA®, I extensively researched any information available and had in-depth discussions with my neurologist and we decided it was the right choice for me.”

— Juan, living with ALS

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# RADICAVA ORS<sup>®</sup> Was Generally Well Tolerated

RADICAVA ORS<sup>®</sup> is the oral formulation of RADICAVA<sup>®</sup> (edaravone) and has a similar safety profile.

The safety profiles of RADICAVA<sup>®</sup> and RADICAVA ORS<sup>®</sup> were established in **500+** patients with ALS in multiple clinical studies.



## IMPORTANT SAFETY INFORMATION (continued)

Do not receive RADICAVA or RADICAVA ORS if you are allergic to edaravone or any of the ingredients in RADICAVA and RADICAVA ORS.

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

- have asthma.
- are allergic to other medicines.
- are pregnant or plan to become pregnant. It is not known if RADICAVA or RADICAVA ORS will harm your unborn baby.

## Side effect profile



The safety of the IV formulation of RADICAVA<sup>®</sup> was evaluated in multiple placebo-controlled studies in 184 patients with ALS.



RADICAVA ORS<sup>®</sup> was generally well tolerated in a 6-month clinical study of 185 patients with ALS.

- The most common side effects were bruising (contusion) [15%], problems with walking (gait disturbance) [13%], and headache [10%]. Fatigue was also reported in 7.6% of patients taking RADICAVA ORS<sup>®</sup>

These are not all of the possible side effects with RADICAVA<sup>®</sup> or RADICAVA ORS<sup>®</sup>.

**Fewer than 6% (11/185) of patients discontinued RADICAVA ORS<sup>®</sup> because of side effects in the 6-month safety study in 185 patients with ALS.**

- Approximately 1% (2/185) of patients discontinued RADICAVA ORS<sup>®</sup> due to gastrointestinal side effects (diarrhea and trouble swallowing)
  - Other reasons for discontinuation in ~1% (2/185) of patients included respiratory failure and muscular weakness

## Other considerations

- RADICAVA ORS<sup>®</sup> and RADICAVA<sup>®</sup> have been used in clinical studies with other approved drugs for ALS, including riluzole
  - Be sure to tell your doctor if you are allergic to other medications and share all of the medications you are taking

The Prescribing Information has no requirement for monitoring kidney or liver function.

IV=intravenous.

Please see full Important Safety Information on page 15 and full Prescribing Information and Patient Information.

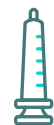
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# Taking RADICAVA ORS® (edaravone)

RADICAVA ORS® offers an oral option that can fit into your routine.



5 mL (teaspoon size) oral dose may take only a few minutes to administer once daily on treatment days<sup>a</sup>



RADICAVA ORS® can be taken orally or via feeding tube



Can be stored at room temperature so you can take it at home or on the go<sup>b</sup>



RADICAVA ORS® contains 1.1 mg of sodium per dose (dietary guidelines recommend less than 2300 mg of sodium per day)



Requires shaking but does not require water or additional mixing steps



RADICAVA ORS® contains sorbitol, an ingredient with a mildly sweet taste

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

<sup>b</sup>Store RADICAVA ORS® upright at room temperature between 68°F-77°F. Protect from light.



## Starter treatment cycle



RADICAVA ORS® is taken once daily for 14 days followed by 14 consecutive days off.

## Maintenance treatment cycle



RADICAVA ORS® is taken on 10 of 14 days followed by 14 consecutive days off each month.

Taking RADICAVA ORS® daily can occur on **any 10 days** in the 14-day treatment period.

## Fasting guidance for RADICAVA ORS®

**RADICAVA ORS® 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 doctor can help guide you on any dosing questions or concerns

Type of meal/supplement consumed	Fasting times before and after administration	
	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

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

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Read the **Instructions for Use** before you take RADICAVA ORS®.

## IMPORTANT SAFETY INFORMATION (continued)

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

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

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

# The JourneyMate Support Program™

## Resources to help on your treatment journey

No matter where you are in your ALS journey—from diagnosis to treatment—the **JourneyMate Support Program™** 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.



### Resource Specialist:

A go-to resource in the **JourneyMate Support Program™** for general information about ALS and RADICAVA ORS® (edaravone).



### Insurance & Access Specialist:

This specialist can help you understand insurance coverage, financial support options, specialty pharmacy options, and the steps to accessing your RADICAVA ORS® prescription.



### 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 throughout your treatment.

To learn more, call 1-855-457-6968 or visit [RadicavaORS.com](http://RadicavaORS.com).

The **JourneyMate Support Program™** offers educational support and resources for patients who are considering or have already been prescribed a Mitsubishi Tanabe Pharma America, Inc. (MTPA) product. An ALS Clinical Educator is an educational resource for patients who have been prescribed an MTPA product. An ALS Clinical Educator is provided by MTPA and VMS 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.

# Support for Veterans With ALS

## VA (Veterans Affairs) benefits

The VA provides assistance and benefits for veterans with ALS, including access to treatment.



*“For unknown reasons, military veterans are more likely to be diagnosed with ALS than the general public. The addition of RADICAVA ORS® to the VA National Formulary symbolizes not only the dedication and recognition of veterans by MTPA and the VA, but also a significant step forward for those in the ALS community in need of an alternate treatment option.”*

— Juan Reyes, US military veteran and patient ambassador for MTPA, living with ALS

To learn more about assistance and benefits for veterans with ALS, visit [ALSVeterans.com](http://ALSVeterans.com).

## IMPORTANT SAFETY INFORMATION (continued)

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## Additional Resources for You

### How RADICAVA® (edaravone) May Help



Click on the video above to watch how RADICAVA® was shown to treat people with ALS.

### RADICAVA ORS® (edaravone) Dosing and Administration



Click on the video above to watch how to prepare and take the medication.

Explore other helpful and informational videos at [RadicavaORS.com](https://RadicavaORS.com).



### IMPORTANT SAFETY INFORMATION (continued)

#### What are the possible side effects of RADICAVA and RADICAVA ORS? (continued)

- 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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### INDICATION

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

The most common side effects include bruising (contusion), problems walking (gait disturbance), and headache.

These are not all the possible side effects of RADICAVA or RADICAVA ORS. **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 [www.fda.gov/medwatch](https://www.fda.gov/medwatch) or Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058.**

Please see full Prescribing Information and Patient Information.



Talk to your doctor today about  
RADICAVA ORS<sup>®</sup> (edaravone).



Actor portrayals.

Once you and your doctor have decided RADICAVA ORS<sup>®</sup> is right for you:

1. Complete a **Benefit Investigation and Enrollment Form (BIF)** with your doctor to understand your insurance coverage and determine when to start treatment.
2. Call the **JourneyMate Support Program<sup>™</sup>** at 1-844-772-4548 to reach an Insurance & Access Specialist once the BIF is completed for any questions you may have.

There are clinical studies that allow patients to continue taking edaravone while on study treatment.

- Let your doctor know about any clinical studies that you are considering joining

Visit [RadicavaORS.com](https://RadicavaORS.com) for more information about ALS and treatment with RADICAVA ORS<sup>®</sup>.

See stories from  
real patients at  
[ShareYourALSStory.com](https://ShareYourALSStory.com).

*“Because my evaluation and diagnosis were at the same time, my doctor presented the option of an ALS drug, RADICAVA<sup>®</sup> (edaravone). It demonstrated...that it could slow the progression of the disease. If you’ve not researched this option, I would encourage you to discuss it with your doctor.”*

— Susan, living with ALS

### IMPORTANT SAFETY INFORMATION *(continued)*

**What are the possible side effects of RADICAVA and RADICAVA ORS?** *(continued)*

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JourneyMate Support Program is a trademark of Mitsubishi Tanabe Pharma America, Inc.

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