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

FOR YOUR MOMENTS BIG AND SMALL

RADICAVA ORS® (edaravone) offers an **oral option** that's formulated to fit your life's routines.

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 13 and full Prescribing Information and Patient Information.

RADICAVA ORS® (edaravone) Is Formulated to Fit Your Life's Routines

RADICAVA ORS® is an oral formulation of edaravone, a treatment for ALS that has been shown to slow the loss of physical function.

RADICAVA ORS® has been **evaluated in several medical studies.**

RADICAVA ORS® can be taken orally or via feeding tube, **without the need for dose adjustment.**

5 mL dose **may take only a few minutes to administer** on treatment days.[a]

Actor portrayals.

ALS can progress rapidly. Beginning treatment with RADICAVA ORS® can be important in slowing the loss of physical function.

[a]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 10 out of 14 days followed by a 14-day drug-free period.

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.

Prioritizing the needs of those with ALS

Building on the legacy of RADICAVA® (edaravone), Mitsubishi Tanabe Pharma America is prioritizing helping people with ALS by continuing to invest in research with edaravone to help meet the needs of the ALS community.

Edaravone has been studied for **over a decade in research and development.**

Wide experience with RADICAVA®

RADICAVA® has been used to treat over 6500 patients with **approximately 1 million days of therapy since approval by the FDA.**[a]

RADICAVA® has been prescribed by over 1500 healthcare providers.[b]

Supporting veterans

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

To learn more about assistance and benefits for veterans with ALS, visit **RadicavaORS.com/VHA**.

[a]Based on cartons sold as of April 2022. One carton equals 1 day of therapy.

[b]Data are based on healthcare provider use of RADICAVA® as of April 2022.

FDA=Food and Drug Administration.

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

Monitoring Progression

ALS is a progressive disease. 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.

There are 4 categories in the ALSFRS-R that align to different areas of the body.

Within each category, there are questions about physical functions, such as swallowing, shortness of breath, dressing and hygiene, climbing stairs, and turning in bed.

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

Actor portrayals.

ALSFRS-R=ALS Functional Rating Scale–Revised.

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).

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

Without treatment, the average rate of decline is about **1 point per month**.

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.

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.

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/ALSFRS-R**.

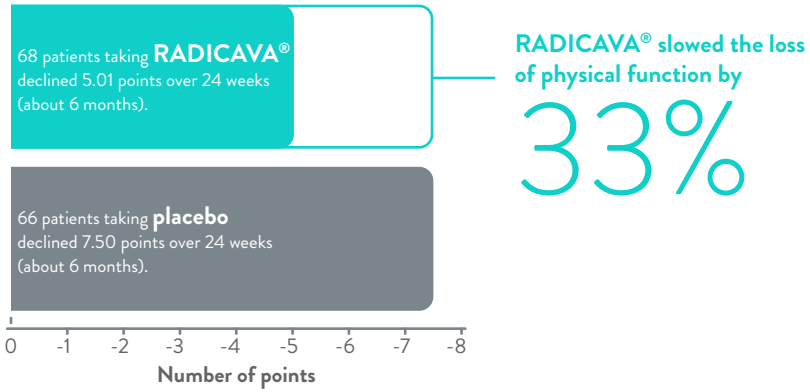
Please see full Important Safety Information on page 13 and full Prescribing Information and Patient Information.

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

How RADICAVA ORS® (edaravone) May Help

RADICAVA ORS® is an oral form of edaravone. RADICAVA® (edaravone) has been shown to slow the loss of physical function by 33% (approximately one-third) vs placebo.

Slowed loss of physical function at 24 weeks



Patients lost fewer points on the ALSFRS-R

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.

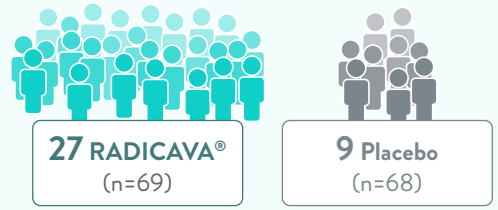
The most common side effects include bruising (contusion), problems walking (gait disturbance), and headache.

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 or Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058.**

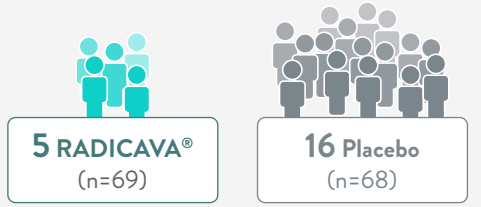
Patients taking RADICAVA® lost fewer points at 24 weeks as measured by the ALSFRS-R.

3X as many patients given RADICAVA® lost **2 or less points**

(39.1% RADICAVA® vs 13.2% placebo)



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



3X as many patients given placebo lost **11 or more points**

(23.5% placebo vs 7.2% RADICAVA®)

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

Please see full Important Safety Information on page 13 and full Prescribing Information and Patient Information.

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

Understanding the Safety Profile of RADICAVA ORS® (edaravone)


Actor portrayals.

RADICAVA ORS® has a similar safety profile as the IV formulation of RADICAVA® (edaravone).

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

Side effect profile:

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

The safety of RADICAVA ORS® was demonstrated in a 24-week 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®

These are not all of the possible side effects with RADICAVA® or RADICAVA ORS®.

IV=intravenous.

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.

Fewer than 6% of patients discontinued RADICAVA ORS® because of side effects in the 24-week safety study in 185 patients with ALS.

- Approximately 1% of patients discontinued RADICAVA ORS® due to gastrointestinal side effects (diarrhea and trouble swallowing)
  - Other reasons for discontinuation (1%) included respiratory failure and muscular weakness

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

Make sure to tell your doctor:

If you have asthma

If you are allergic to other medications

If you are pregnant or intend to become pregnant

If you are breastfeeding or intend to breastfeed

All of the medications you are taking

Please see full Important Safety Information on page 13 and full Prescribing Information and Patient Information.

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

Taking RADICAVA ORS® (edaravone)

Designed with ALS patients in mind

5 mL oral dose may take only a few minutes to administer on treatment days[a]

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[b]

Requires shaking but does not require water or additional mixing steps

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

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

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

[b]Store RADICAVA ORS® upright at room temperature between 68°F–77°F. Protect from light.

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.

14 **days on**
14 **days off**

First treatment cycle

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

10 **out of 14 days on**
14 **days off**

Subsequent treatment cycles

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.

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

Fasting guidance for RADICAVA ORS®

	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**

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

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

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.

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, site of care, and 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 personal 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.

*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.*

INDICATION

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IMPORTANT SAFETY INFORMATION

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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.
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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 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).

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Please see full Prescribing Information and Patient Information.

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

Talk to your doctor today about RADICAVA ORS® (edaravone).

- RADICAVA ORS® is an oral formulation of a proven ALS treatment—RADICAVA® (edaravone)
- RADICAVA® has been shown to slow the loss of physical function on the ALSFRS-R scale by 33% (approximately one-third) vs placebo at 24 weeks
- The most common side effects with RADICAVA® and RADICAVA ORS® were bruising (contusion) [15%], problems with walking (gait disturbance) [13%], and headache [10%]

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

- Talk to your doctor about any clinical studies that you are considering joining

Visit **RadicavaORS.com** for more information about ALS and treatment with RADICAVA ORS®.

Once you and your doctor have decided RADICAVA ORS® is right for you:

1. Work with your doctor to complete a Benefit Investigation Form (BIF) to understand your insurance coverage and determine when to start treatment.
2. Call the ***JourneyMate Support Program***™ at 1-855-457-6968 once the benefits form is completed for any questions you may have.

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.

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Mitsubishi Tanabe Pharma America