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.

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.
WHY RADICAVA® ORS®?

ALSFRS-R

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

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.

*Based on cartons sold as of April 2022. One carton equals 1 day of therapy.

**Data are based on healthcare provider use of RADICAVA® as of April 2022.

FDA=Food and Drug Administration.

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

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

- 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.

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.

RADICAVA® has been prescribed by over 1500 healthcare providers.

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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.

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.

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

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.

To see how the ALSFRS-R works and the impact of losing or keeping points, visit RadicavaORS.com/ALSFRS-R.

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).

IMPORTANT SAFETY INFORMATION (continued)

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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.

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

Slowed loss of physical function at 24 weeks

- 68 patients taking RADICAVA® declined 5.01 points over 24 weeks (about 6 months).
- 66 patients taking placebo declined 7.50 points over 24 weeks (about 6 months).

RADICAVA® slowed the loss of physical function by 33%.

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.

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

Understanding the Safety Profile of RADICAVA ORS® (edaravone)

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 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®.

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

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- 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.

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®**

<table>
<thead>
<tr>
<th>Type of meal/supplement consumed</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-fat meal (800-1000 calories, 50% fat)</td>
<td>8 hours</td>
<td>1 hour</td>
</tr>
<tr>
<td>Low-fat meal (400-500 calories, 25% fat)</td>
<td>4 hours</td>
<td>1 hour</td>
</tr>
<tr>
<td>Caloric supplement (250 calories, eg, protein drink)</td>
<td>2 hours</td>
<td>1 hour</td>
</tr>
</tbody>
</table>

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

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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.

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Please see full Prescribing Information and Patient Information.
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®.

IMPORTANT SAFETY INFORMATION (continued)

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Mitsubishi Tanabe Pharma America

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