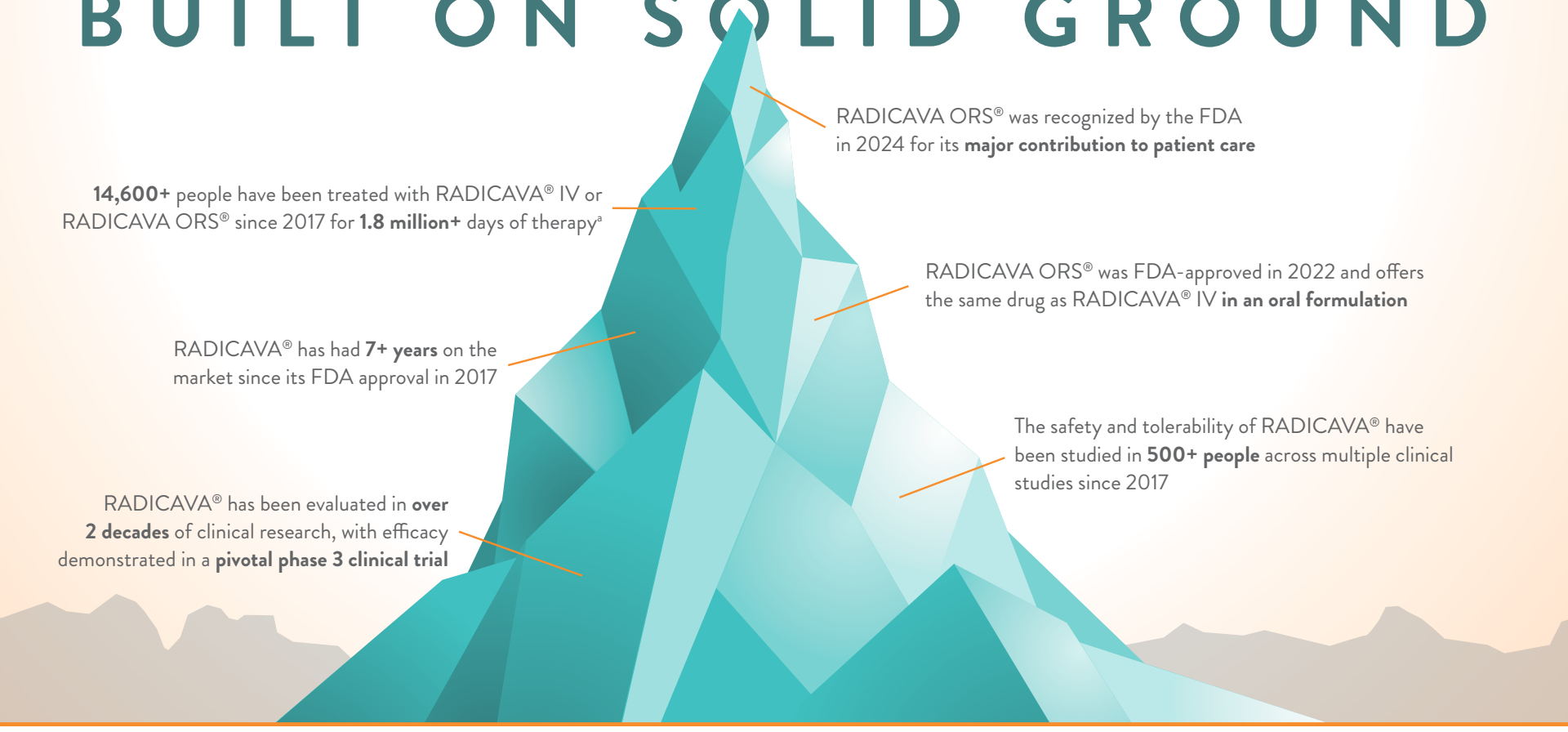
Radicava ORS® (edaravone) Oral Suspension 105mg/5mL

INDICATION

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

BUILT ON SOLID GROUND



[a]Based on RADICAVA ORS® and RADICAVA® IV prescriptions submitted in the US as of April 2024. Not independently verified.
IV=intravenous; FDA=Food and Drug Administration.

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.

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

IMPORTANT SAFETY INFORMATION

Before you receive 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.
- 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.

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

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

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

RADICAVA ORS®—A Foundation of Clinical and Real World Experience

In ALS, every point matters

Losing or keeping a single point on the ALSFRS-R can have a significant impact on those living with ALS. That's why the pivotal phase 3 clinical trial of RADICAVA® was specifically designed to measure change in physical function assessed by the ALSFRS-R.

Learn how ALSFRS-R works

In the clinical study, RADICAVA® showed a statistically significant change in physical function measured by the ALSFRS-R compared to those not taking RADICAVA® at 24 weeks

RADICAVA® slowed the loss of physical function at 24 weeks (about 6 months), where patients who did not receive RADICAVA® declined more rapidly in physical function, having lost an average of 2.49 points more.

ALSFRS-R=ALS Functional Rating Scale–Revised.

IMPORTANT SAFETY INFORMATION

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 and RADICAVA ORS and can happen after your medication has been given.

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

Researchers determined that RADICAVA® outperformed placebo (a treatment that contains no actual medicine) significantly.
This was indicated by using a "*P* value," a statistical form of measurement.

***P* value indicates how probable the results are due to chance**

***P*<0.001**	**Very strong statistical evidence** Meaning there is less than a 1 in 1000 probability that the results are due to random chance
***P*≤0.05**	**Statistical difference** Meaning there is less than 5% probability that the results are due to random chance
***P*>0.05**	**No statistical difference** Meaning no statistical difference between groups

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

RADICAVA ORS®—A Foundation of Clinical and Real World Experience

RADICAVA ORS® offers the same drug as RADICAVA® in an oral formulation

RADICAVA® resulted in a **33% less decline** in physical function vs placebo (*P*=0.0013).

A change in the ALSFRS-R of 20% to 25% or greater is considered clinically meaningful according to the Northeast ALS Consortium (NEALS).

RADICAVA ORS® is generally well tolerated

- The safety profile of RADICAVA® 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

The most common side effects for patients taking RADICAVA® 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®.

IMPORTANT SAFETY INFORMATION

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

- 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.

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

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

RADICAVA ORS®—A Foundation of Clinical and Real World Experience

RADICAVA ORS® is formulated to fit your life's routines

- Can be taken orally or via feeding tube
- 5 mL dose may only take a few minutes to administer on treatment days[b]
- Only dosed 10 out of 14 days, followed by a 14-day drug-free period – to allow for more treatment-free days

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

In 2024, FDA recognized RADICAVA ORS® as a **major contribution to patient care** as it provides a clinically superior option for patients—due to its oral suspension route of administration that provides a less burdensome option vs intravenous administration of previously approved RADICAVA® IV.

From 2019 to March 2024, **RADICAVA ORS® is 1 of 4 medications given this recognition**.

IMPORTANT SAFETY INFORMATION

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).

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

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

Ask your doctor about the vast clinical experience of RADICAVA ORS® and learn more at RadicavaSolidGround.com

IMPORTANT SAFETY INFORMATION

These are not all the possible side effects of RADICAVA or RADICAVA ORS. Call your healthcare provider for medical advice about side effects. You may report side effects to Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see additional Important Safety Information throughout and full Prescribing Information and Patient Information.

Mitsubishi Tanabe Pharma America