

What to Expect in Your RADICAVA ORS® (edaravone) Shipments





Maintenance Dose

For illustration purposes only. Not actual size.

Specialty Pharmacy will ship the medication directly to your home.

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.
- 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.

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) Starter Kit:

First Shipment =

2 cartons each containing:

- One 35 mL bottle (7 doses)
- 2 reusable oral syringes
- 1 bottle adapter
- 1 Prescribing Information,



Note: The bottles are not completely filled with liquid medication.



First treatment cycle

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

IMPORTANT SAFETY INFORMATION (continued)

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 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.

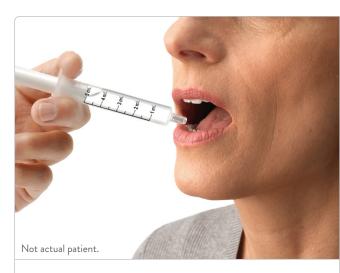
RADICAVA ORS® Maintenance Kit:

Subsequent Shipments

1 carton containing:

- One 50 mL bottle (10 doses)
- 2 reusable oral syringes
- 1 bottle adapter
- 1 Prescribing Information, including Instructions for Use





Watch the **Dosing and Administration Video** for more information.

Note: The bottle is not completely filled with liquid medication.



Subsequent treatment cycles

RADICAVA ORS® is taken once daily for 10 days within a 14-day period followed by 14 consecutive days off.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of 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).

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

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



Taking RADICAVA ORS® (edaravone)

- The first month Starter Kit has 2 bottles
- After that, it's 1 bottle = 1 month of treatment (maintenance dose)
- 5 mL (teaspoon size) dose taken by mouth or via feeding tube
- No water or additional mixing steps needed (shaking required)

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



Take RADICAVA ORS® as prescribed by your healthcare provider.

Read the <u>Instructions for Use</u> before you take 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.

Fasting guidance for RADICAVA ORS®

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.

IMPORTANT SAFETY INFORMATION (continued)

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.

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 <u>www.fda.gov/medwatch</u> or Tanabe Pharma America, Inc. at 1-888-292-0058.

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



Tanabe Pharma America

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