



# Dosing and Administration Guide

**RADICAVA (ra di ká vah) ORS<sup>®</sup> Oral Suspension**

## INDICATION

RADICAVA ORS<sup>®</sup> (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

## IMPORTANT SAFETY INFORMATION

**Do not receive RADICAVA ORS<sup>®</sup> (edaravone) if you are allergic to edaravone or any of the ingredients in RADICAVA ORS.**

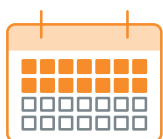
**Please see Important Safety Information on back cover and the full Prescribing Information and Patient Information, also available at [www.radicavaors.com](http://www.radicavaors.com).**

## Dosing Schedule

RADICAVA ORS® has 2 different dosing schedules—one for the first cycle and one for all of the following cycles (cycles 2+). Take RADICAVA ORS® as prescribed by your healthcare provider.

### CYCLE 1

Getting started on RADICAVA ORS®



14 consecutive days on  
14 consecutive days off

If you have been prescribed the Starter Kit, you will receive 2 (35 mL) bottles of RADICAVA ORS® to be used for your first 14-day treatment cycle. Only open the second bottle when you have finished the first bottle.

### CYCLES 2+

Continuing on RADICAVA ORS®



10 out of 14 days on  
14 consecutive days off

If you have not been prescribed the Starter Kit, you will receive 1 bottle (50 mL) of RADICAVA ORS® for each treatment cycle that includes 10 days of treatment within a 14-day period.

## When to take RADICAVA ORS®

RADICAVA ORS® should be taken in the morning on an empty stomach after not eating (fasting) overnight for 8 hours.

- Take at least 1 hour before eating or drinking anything except water
- If you have any dietary concerns, talk to your doctor
- RADICAVA ORS® is to be taken orally or by using a feeding tube. See the Instructions for Use for further details on how to properly take RADICAVA ORS®

### IMPORTANT INFORMATION

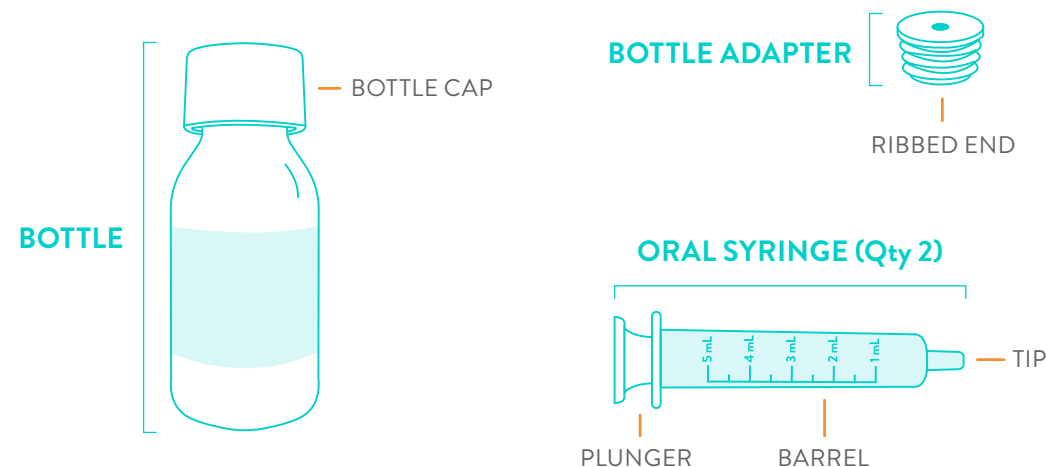
- Always measure your prescribed dose of RADICAVA ORS® using the oral syringe provided
- Ask your healthcare provider or pharmacist any questions you may have about how to measure your prescribed dose
- If you miss a dose, do not take 2 doses of RADICAVA ORS® the next day
- Do not take a dose of RADICAVA ORS® on days 15 through 28 of the dosing cycle

## How to Prepare Your Dose

Each RADICAVA ORS® carton contains:

- 1 RADICAVA ORS® bottle
- 1 bottle adapter
- 2 (5 mL) reusable oral syringes

Use a new 5 mL oral syringe and bottle adapter when using a new bottle of RADICAVA ORS®.



When you open the bottle of RADICAVA ORS® for the first use, write the date on the bottle label. Throw away (discard) any RADICAVA ORS® that is not used within 15 days after opening the bottle or within 30 days from the date of shipment shown on the carton pharmacy label, whichever happens first.

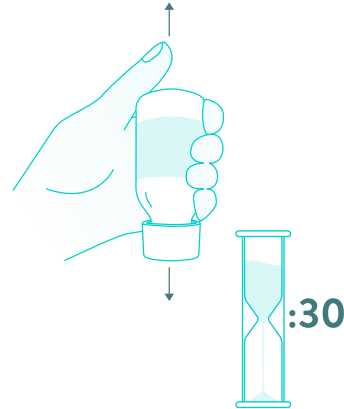
[View the RADICAVA ORS® Dosing and Administration Video.](#)

Please see Important Safety Information on back cover and full [Prescribing Information](#) and [Patient Information](#).

## Step 1: Shake for 30 Seconds Before Use

- Prior to opening the bottle before each use, turn the bottle upside down (invert) and shake it vigorously up and down for at least **30 seconds**
- Look at the liquid to make sure it is mixed well
- If you see any small pieces at the bottom of the bottle, invert the bottle and shake for another **30 seconds** or until you can no longer see the pieces at the bottom

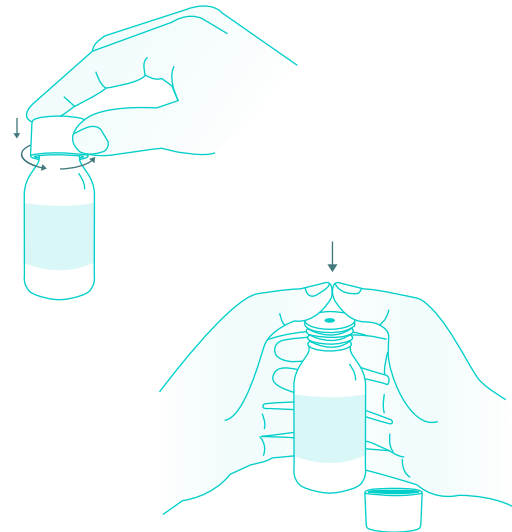
People who have problems using their hands may need assistance to draw up and take the correct dose of RADICAVA ORS® (edaravone).



## Step 2: Insert Adapter

- Open the bottle by **firmly pressing down** on the bottle cap and turning it counterclockwise (to the left)
- Place the open bottle upright on a flat surface. **Do not** throw away the bottle cap. You will need to replace it after taking each dose
- **For first time use of a bottle**, insert the ribbed end of the bottle adapter into the bottle by firmly pressing it in as far as it will go
- **Do not** remove the bottle adapter once it is inserted. The bottle cap will still fit with the adapter inside. **Do not** remove the bottle adapter

**NOTE:** Only use the bottle adapter and 2 reusable 5 mL oral syringes provided with the bottle.



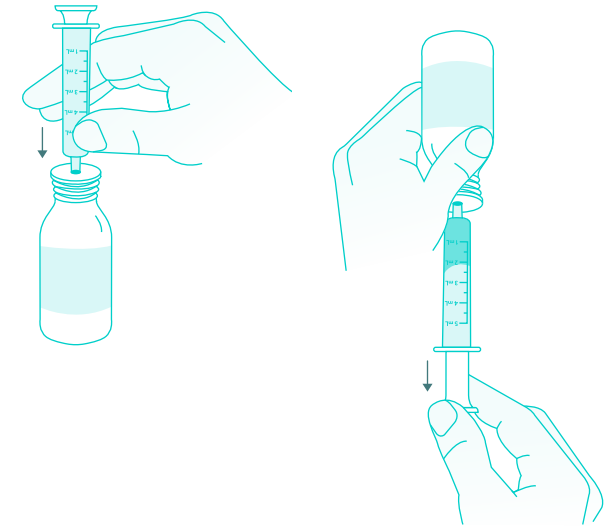
**Radicava ORS®**  
(edaravone) Oral Suspension  
105mg/5mL

Please see Important Safety Information on back cover and full [Prescribing Information](#) and [Patient Information](#).

## Step 3: Insert Syringe

- **Remove the oral syringe from the plastic wrap and make sure the plunger is inserted all the way into the barrel**
- Push the plunger toward the tip of the syringe to remove excess air
- Insert the syringe into the opening of the bottle adapter until it is firmly in place
- Turn the bottle upside down and slowly pull the plunger to remove a small amount of liquid

**NOTE:** Always measure your prescribed dose of RADICAVA ORS® using the oral syringe provided.

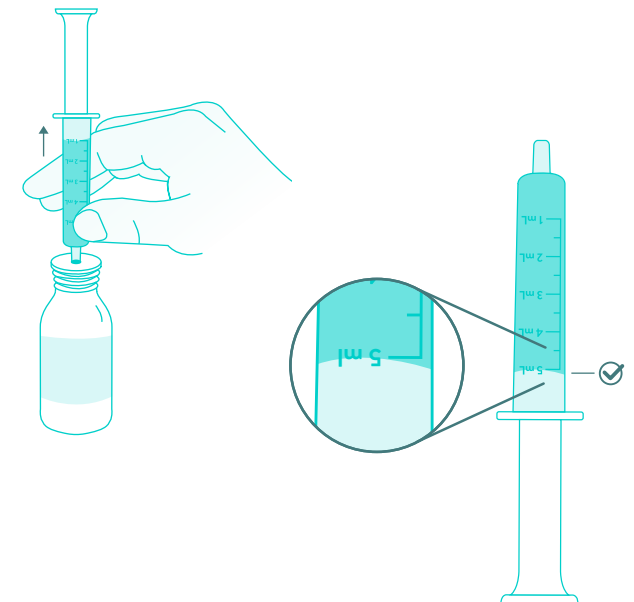


## Step 4: Fill to 5 mL and Remove Syringe

- Keep the bottle upside down and pull the plunger until it goes to the last line (5 mL)
- While keeping the plunger in the same position, turn the bottle upright, and place it carefully on a flat surface
- Remove the oral syringe by gently twisting or pulling it out from the bottle
- Double-check the amount of medicine in the syringe before moving on to the next step

**NOTE:** Do not remove the syringe while the bottle is upside down (medicine may leak out from the adapter).

**NOTE:** If the dose is not correct, reinsert the tip of the syringe firmly into the bottle adapter and push the plunger all the way in so the medicine flows back into the bottle. Turn the bottle upside down and repeat Step 4.

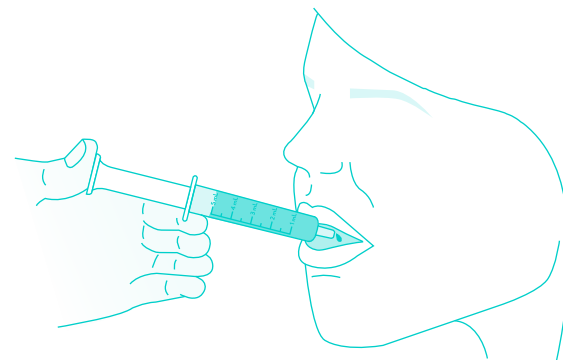


If you are taking RADICAVA ORS® through a feeding tube, please skip to Step 9.



## Step 5: Take Medicine

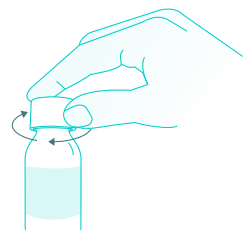
- Place the tip of the oral syringe in the mouth and aim toward the inside of the cheek
- Slowly press down on the plunger until the oral syringe is empty
- Swallow all of the medicine
- If needed, you can use up to 8 ounces, or 1 cup, of water to help swallow the medicine



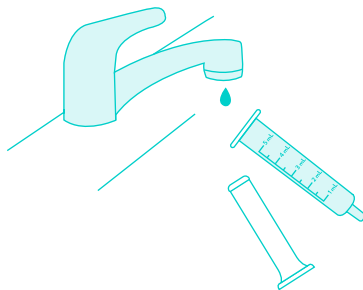
**NOTE:** It is normal for a small amount of medicine to remain in the tip of the syringe after taking.

## Steps 6-8: Wash and Store

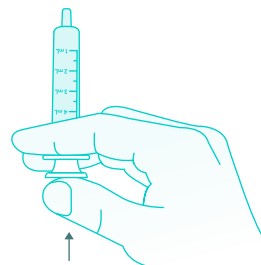
**Step 6:** Leave the bottle adapter inside the bottle and place the bottle cap on the bottle, turning the cap clockwise (to the right) to close. Keep bottle tightly closed between each use.



**Step 7:** Remove the plunger from the syringe barrel by pulling the plunger and the barrel away from each other. **Rinse the plunger and barrel with water only.** Allow it to air dry.



**Step 8:** When the plunger and barrel are dry, put the plunger back into the oral syringe barrel. **Do not throw away the oral syringe.** Store the syringe in a clean, dry place.



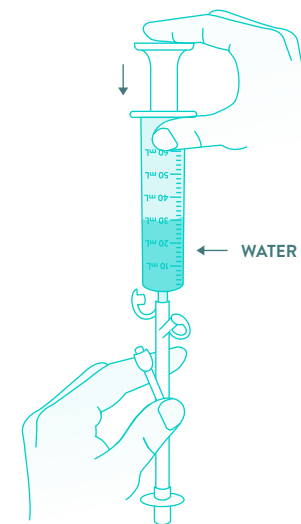
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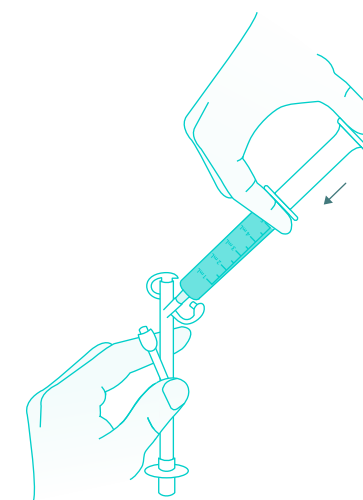
## Steps 9-11: How to Take RADICAVA ORS® Through a Feeding Tube

Complete Steps 1 through 4 to prepare your dose.

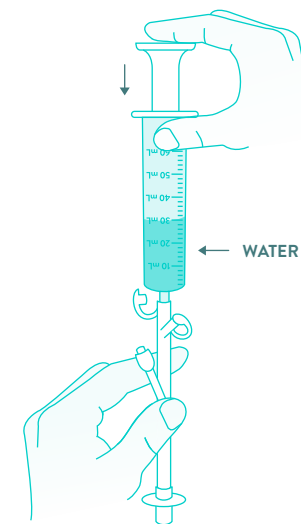
**Step 9:** Using a catheter-tip syringe, flush the feeding tube with 1 ounce (30 mL) of water before your dose.



**Step 10:** Place the oral syringe provided (containing 5 mL of RADICAVA ORS®) into the feeding tube. Slowly push down the plunger until the syringe is empty.



**Step 11:** Using a catheter-tip syringe, flush the feeding tube with 1 ounce (30 mL) of water after taking the dose of RADICAVA ORS®.



Follow Steps 6-8 for directions on closing the bottle and washing and storing the oral syringe.

### IMPORTANT THINGS TO REMEMBER

- When storing, keep the bottle upright and tightly closed between each use and protect from light
- Keep at room temperature between 68°F to 77°F
- Throw away any RADICAVA ORS® that is not used within 15 days after opening the bottle
- Do not share RADICAVA ORS® with anyone else
- Keep RADICAVA ORS® out of the reach of children
- Call your doctor for medical advice about any side effects you may be experiencing



## 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.

### **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.
- 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.

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 [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or Tanabe Pharma America, Inc. at 1-888-292-0058.**

Please see the full [Prescribing Information](#) and [Patient Information](#), also available at [www.radicavaors.com](http://www.radicavaors.com).

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