

PATIENT INFORMATION
RADICAVA (ra di ká vah)
(edaravone) injection
for intravenous use
RADICAVA ORS (ra di ká vah o r s)
(edaravone) oral suspension

What are RADICAVA and RADICAVA ORS?

RADICAVA and RADICAVA ORS are prescription medicines used to treat people with amyotrophic lateral sclerosis (ALS). It is not known if RADICAVA or RADICAVA ORS are safe and effective in children.

Do not receive RADICAVA or RADICAVA ORS if you are allergic to edaravone or any of the ingredients in RADICAVA and RADICAVA ORS. See the end of this leaflet for a complete list of 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.
 - 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.

How will I receive RADICAVA?

- You will be prescribed RADICAVA by a healthcare provider and told how often you will receive RADICAVA.
- RADICAVA will be given by intravenous (IV) infusion into your vein.
- It takes about 1 hour to receive the full dose of RADICAVA.
- Your healthcare provider will monitor you closely during your treatment with RADICAVA.

How will I take RADICAVA ORS?

- See the detailed **Instructions for Use** on how to take RADICAVA ORS at the end of this Patient Information leaflet.
- You will be prescribed RADICAVA ORS by a healthcare provider and told how often you will take RADICAVA ORS.
- RADICAVA ORS is to be taken by mouth or by using a feeding tube.
- RADICAVA ORS should be taken in the morning on an empty stomach. You should stop eating at bedtime.
 - **Do not** eat or drink anything 8 hours before each dose of RADICAVA ORS if you eat a high-fat meal.
 - **Do not** eat or drink anything 4 hours before each dose of RADICAVA ORS if you eat a low-fat meal.
 - **Do not** eat or drink anything 2 hours before each dose of RADICAVA ORS if you take a calorie supplement.
- You should wait at least 1 hour after taking your medicine before eating or drinking anything except water.

What are the possible side effects of RADICAVA and RADICAVA ORS?

RADICAVA and RADICAVA ORS may cause serious side effects including:

1. Hypersensitivity (allergic) reactions. Hypersensitivity reactions have happened in people receiving RADICAVA or taking RADICAVA ORS and can happen after your medicine has been given. 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, face
- fainting
- breathing problems
- dizziness
- itching
- wheezing

2. Sulfite allergic reactions. 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 allergic reactions, for example, 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, face
- wheezing
- trouble breathing or swallowing
- dizziness
- fainting
- itching
- 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.

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

These are not all the possible side effects of RADICAVA and RADICAVA ORS. For more information, ask your healthcare provider or pharmacist.

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.

What are the ingredients in RADICAVA and RADICAVA ORS?

Active ingredient: edaravone

RADICAVA Inactive ingredients: L-cysteine hydrochloride hydrate, sodium bisulfite, sodium chloride, phosphoric acid, and sodium hydroxide.

RADICAVA ORS Inactive ingredients: L-cysteine hydrochloride hydrate, polyvinyl alcohol, simethicone emulsion, sodium bisulfite, sorbitol, and xanthan gum. Phosphoric acid and sodium hydroxide are added to adjust to pH 4.

Marketed and distributed by: Mitsubishi Tanabe Pharma America, Inc., a US subsidiary of Mitsubishi Tanabe Pharma Corporation, 525 Washington Blvd., Suite 400, Jersey City, NJ 07310

For more information, go to www.Radicava.com or call 1-888-292-0058.

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This Patient Information has been approved by the U.S. Food and Drug Administration

Issued: 05/2022