

PATIENT INFORMATION
RADICAVA (phonetic spelling)
(edaravone injection)
for intravenous infusion

What is RADICAVA?

RADICAVA is a prescription medicine used to treat people with Amyotrophic Lateral Sclerosis (ALS). It is not known if RADICAVA is safe and effective in children.

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

Before you receive RADICAVA, 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 will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if RADICAVA passes into your breastmilk. You and your healthcare provider should decide if you will receive RADICAVA 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. 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 tell you how often you will receive RADICAVA.
- Your healthcare provider will monitor you closely during your treatment with RADICAVA.

What are the possible side effects of RADICAVA?

RADICAVA may cause serious side effects including:

1. Hypersensitivity (allergic) reactions. Hypersensitivity reactions have happened in people receiving RADICAVA and can happen after your infusion is finished. Tell you healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms:

- hives
- breathing problems
- itching
- swelling of the lips, tongue, face
- dizziness
- wheezing
- fainting

2. Sulfite allergic reactions. RADICAVA 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 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 you healthcare provider right away or go to the nearest emergency room if you have any of the following symptoms:

- hives
- trouble breathing or swallowing
- itching
- swelling of the lips, tongue, face
- dizziness
- asthma attack (in people with asthma)
- wheezing
- fainting

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

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

These are not all the possible side effects of RADICAVA. Call your healthcare provider for medical advice about side effects.

You may report side effects to MT Pharma America, Inc. at 1-888-292-0058 or FDA at 1-800-FDA-1088 or

www.fda.gov/medwatch.

What are the ingredients in RADICAVA?

Active ingredient: edaravone

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

Marketed and distributed by: MT 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.

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

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