Radicava (edaravone)

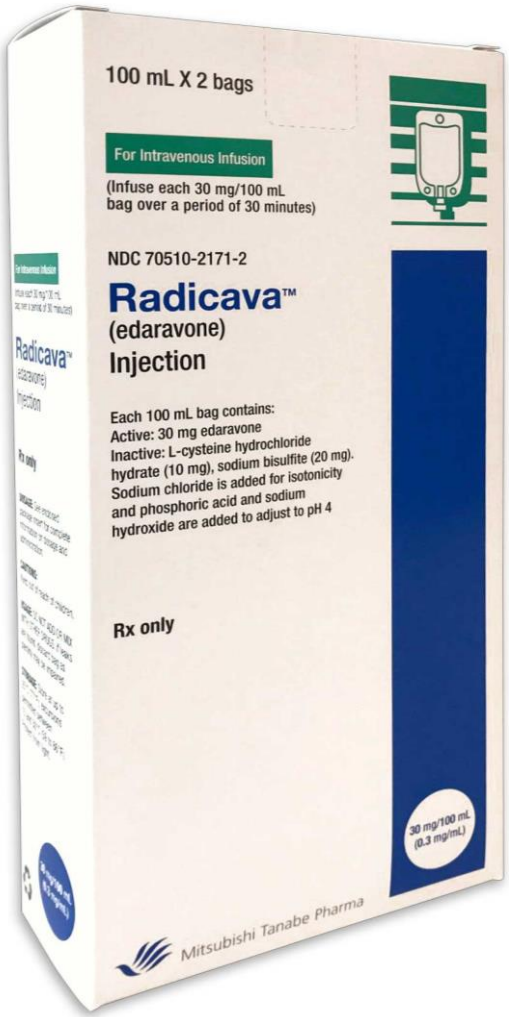
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Radicava
- **Generic name:** Edaravone
- **Pharmacological class:** Free radical scavenger
- **Strength and Formulation:** 30mg/100mL; soln for IV infusion; contain sulfites
- **Manufacturer:** Mitsubishi Tanabe Pharma America
- **How supplied:** Single-dose bags—1, 2
- **Legal Classification:** Rx

RADICAVA


100 mL X 2 bags
For Intravenous Infusion
(Infuse each 30 mg/100 mL bag over a period of 30 minutes)
NDC 70510-2171-2
Radicava™
(edaravone)
Injection
Each 100 mL bag contains:
Active: 30 mg edaravone
Inactive: L-cysteine hydrochloride hydrate (10 mg), sodium bisulfite (20 mg). Sodium chloride is added for isotonicity and phosphoric acid and sodium hydroxide are added to adjust to pH 4
Rx only
30 mg/100 mL (0.3 mg/mL)
Mitsubishi Tanabe Pharma

Indications

- Amyotrophic lateral sclerosis (ALS)

Dosage & Administration

- Give as IV infusion over 60mins
- **Initial cycle**: 60mg (given as two consecutive 30mg infusions) daily for 14 days, followed by 14 days off
- **Subsequent cycles**: 60mg daily for 10 days out of 14-day periods, followed by 14 days off

Considerations for Special Populations

- **Pregnancy:** Inadequate data on the developmental risk in pregnant women
- **Nursing mothers:** Consider benefits and adverse effects on the breastfed infant
- **Pediatric:** Not established
- **Geriatric:** No overall differences in safety or efficacy

Warnings/Precautions

- Monitor for **hypersensitivity** reactions; discontinue and treat if occur
- Asthma
- Sulfite sensitivity

Adverse Reactions

- Confusion
- Gait disturbance
- Headache
- Dermatitis
- Eczema
- Respiratory failure/disorders
- Hypoxia
- Glycosuria
- Tinea infection
- Hypersensitivity reactions
- Anaphylaxis

Mechanism of Action

- The mechanism by which Radicava exerts its therapeutic effect in patients with ALS is unknown

Clinical Studies

- The efficacy of Radicava was established in a 6-month, randomized, placebo-controlled, double-blind study (n=137) in Japanese patients with ALS
- Patients had ALS Functional Rating Scale – Revised (ALSFRS-R) score of ≥2, normal respiratory function, definite or probable ALS based on El Escorial revised criteria, and disease duration of ≤2 years

Clinical Studies

- The study enrolled 69 patients in the Radicava arm and 68 in the placebo arm
  - Baseline characteristics were similar between the two groups
  - Over 90% of patients in each group were receiving riluzole

Clinical Studies

- Radicava was administered as IV infusion of 60mg over 60mins
- The **primary efficacy endpoint** was the change between the treatment arms in the ALSFRS-R total scores from baseline to Week 24

Clinical Studies

- The decline in ALSFRS-R scores from baseline was significantly less in the Radicava arm (-5.01±0.64) vs. the placebo arm (-7.50±0.66) (*P*=0.0013)
  - Treatment difference 2.49 (95% CI: 0.99, 3.98; *P*=0.0013)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/radicava/drug/34722/