Radicava® (edaravone) IV infusion 30mg/20mL

Quick Guide

for RADICAVA® (edaravone) IV infusion*

1

Approved Indication

RADICAVA is indicated in adults with a diagnosis of amyotrophic lateral sclerosis (ALS) who are independent in activities of daily living with normal respiratory function and where treatment is initiated within two years of onset.

Efficacy has not been demonstrated in patients outside of this defined population.

2

Preparation

Each clear glass ampoule contains 30 mg of edaravone in 20 mL concentrated solution for injection.

Dilute 60 mg of RADICAVA IV infusion (two ampoules) with 100 mL of 0.9% sodium chloride before each infusion.

RADICAVA IV infusion is administered as an intravenous infusion over a **60-minute period.**

3

Dosing Schedule

First Cycle

14 consecutive **days on**

14 consecutive **days off**

The first cycle includes 14 days of daily infusions, followed by a 14-day drug-free period.

Ongoing Cycles

10 out of **14 days on**

14 consecutive **days off**

Subsequent cycles consist of 10 days of infusions within a 14-day period, followed by a 14-day drug-free period.

The following cycle is to be started at 28 days after the first dosing date of the previous cycle.

*IV = intravenous.

teva

Radicava®
(edaravone) IV infusion 30mg/20mL

4

General Precautions

1. Hypersensitivity reactions
2. Sulfite allergic reactions
3. Sodium content
4. The elderly

For more information on these precautions, please refer to the full Product Information (PI)[1]

5

Adverse Reactions

Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction.

Hypersensitivity reactions and cases of anaphylaxis have been reported in spontaneous post-marketing reports with edaravone.

RADICAVA IV infusion contains sodium bisulphite, a sulphite that can cause allergic-type reactions.

The most frequently reported adverse events (AEs) with RADICAVA IV infusion (≥5% and greater than placebo) across three Phase III clinical studies were contusion, gait disturbance, headache, eczema and contact dermatitis. For a complete list of AEs, please refer to the full Product Information (PI)[1]

6

Observations

Observe for allergic reaction, particularly if history of allergy or asthma. If hypersensitivity reactions or any other abnormality are observed, RADICAVA IV infusion administration should be discontinued, treat as per standard of care and monitor until condition resolves.

PBS Information: This product is listed on the PBS as a Section 100 item.
Refer to PBS Schedule for full authority information[2].

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

PLEASE REVIEW PRODUCT INFORMATION BEFORE PRESCRIBING. The Product Information can be accessed at https://rss.medsinfo.com.au/tb/pi.cfm?product=tbpradic or from Medical Information on 1800 AU TEVA (1800 28 8382) or by scanning the QR code.

Reference: 1. Product Information RADICAVA IV infusion, Australia. **2.** Pharmaceutical Benefits Scheme (PBS). Available at: https://www.pbs.gov.au/

Teva Pharma Australia Pty Ltd ABN 41 169 715 664 Level 1, 37 Epping Road, Macquarie Park, NSW, 2113 Australia.
Phone: 1800 AU TEVA (1800 288 382) www.tevapharma.com.au Date of Preparation: April 2025. RAD-AU-NP-00020. Date of Expiry: April 2027.