▼ 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.

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

Every **moment** matters

Prescribing RADICAVA Intravenous (IV) Infusion

This booklet provides essential information on RADICAVA IV infusion's efficacy, dosing, administration and access to support you in prescribing treatment.

This material is intended for healthcare professionals only. It is not for public distribution or use.

teva

Understanding RADICAVA IV infusion

RADICAVA (edaravone) IV infusion is a Therapeutic Goods Administration (TGA) approved medication in Australia for the treatment of amyotrophic lateral sclerosis (ALS) in certain patients. The active ingredient, edaravone, functions as a free radical scavenger to reduce oxidative stress, but its exact mechanism of action in ALS is not fully understood.[1]

Indication for use

RADICAVA IV infusion is indicated in adults with a diagnosis of ALS who are independent in activities of daily living with normal respiratory function and where treatment is initiated within two years of disease onset.[1]

Efficacy has not been demonstrated in patients outside of this defined population.[1]

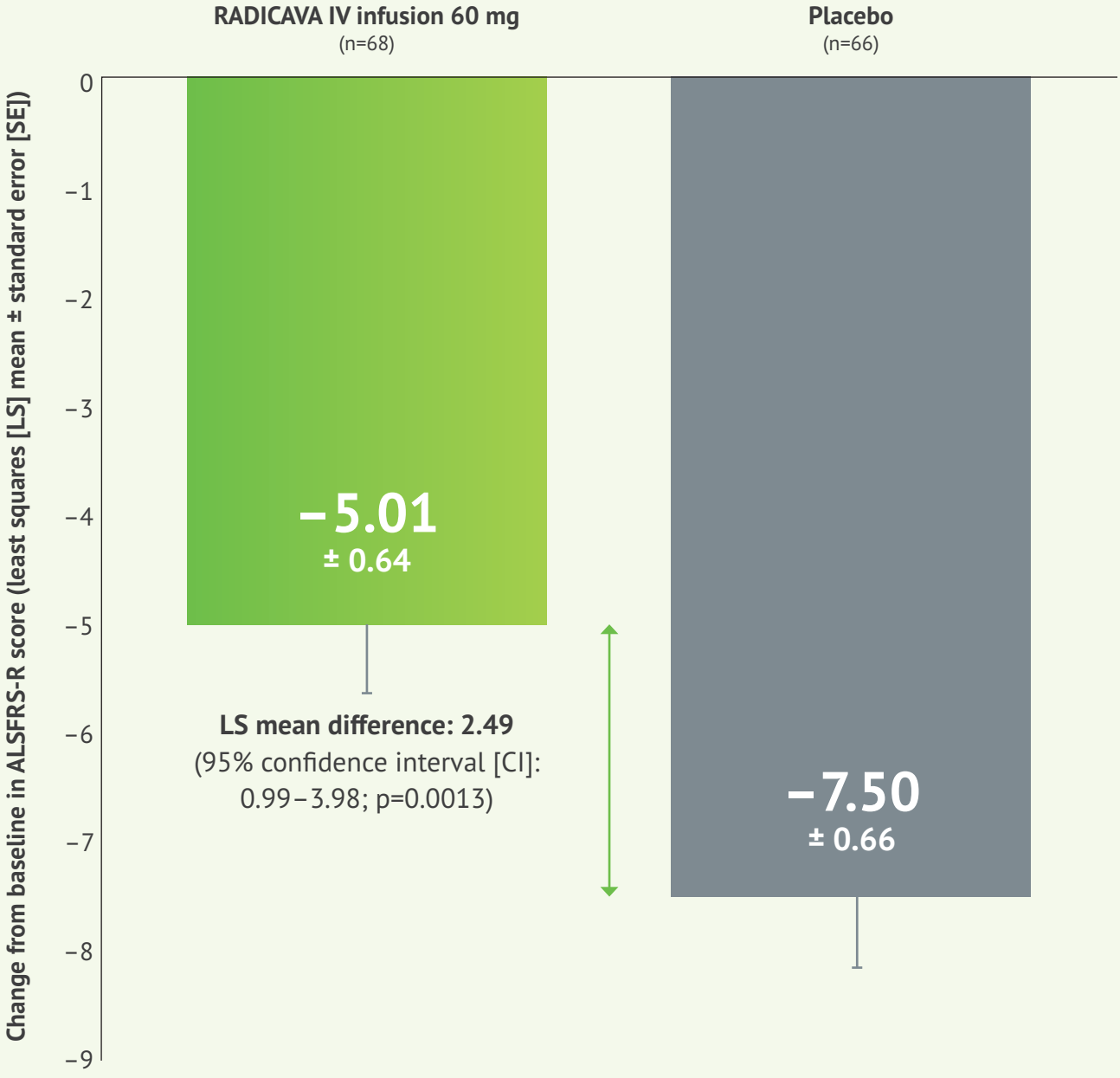
RADICAVA IV infusion is available as a 30 mg / 20 mL concentrated solution for injection[1]

Supplied as a clear, colourless, sterile solution in glass ampoules. Pack size: 10 ampoules, each containing 30 mg/20 mL. Store below 25° C.[1]

Efficacy of RADICAVA IV infusion

In a pivotal Phase III trial, RADICAVA IV infusion demonstrated a significantly smaller decline in Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) scores compared to placebo (p=0.0013).[2]

The decline in ALSFRS-R total scores at Week 24 (primary endpoint)*[2]



Adapted from Edaravone (MCI-186) ALS 19 Study Group. 2017.[2]

*For patients with missing values at the end of cycle 6, data were imputed using the last observation carried forward (LOCF) method, as long as they had completed at least cycle 3.[2]

33% less change in ALSFRS-R scores from baseline vs placebo at 24 weeks[2]

Study design: A 24-week, randomised, placebo-controlled, Phase III clinical trial evaluating the efficacy of RADICAVA IV infusion in Japanese patients with ALS. The study included 137 patients aged 20–75 years with definite or probable ALS according to the El Escorial and the revised Airlie House criteria, ≥2 points on all ALSFRS-R items, forced vital capacity ≥80%, and a disease duration of ≤2 years, with a decline of 1–4 points in ALSFRS-R during a 12-week observation period. Patients were randomised to receive either 60 mg IV RADICAVA IV infusion or saline placebo, with an initial 14-day daily dosing cycle followed by a 14-day drug-free period (cycle 1), and subsequent cycles of 10 days of daily dosing within a 14-day period followed by 14-day drug-free periods (cycles 2–6). The primary endpoint was the change in total ALSFRS-R scores from baseline to Week 24 between treatment groups. Safety was assessed in all patients who received at least one infusion and had one post-baseline assessment.[2]

Tolerability of RADICAVA IV infusion

The safety profile has been shown in pooled placebo-controlled trials involving 184 ALS patients who received 60 mg RADICAVA IV infusion in treatment cycles for 6 months.[1]

The most frequently reported adverse events with RADICAVA IV infusion (≥3% and greater than placebo) across three Phase III clinical studies[1]

Adverse event	RADICAVA IV infusion (N=184), n (%)	Placebo (N=184), n (%)
Contusion	27 (14.7)	16 (8.7)
Gait disturbance	23 (12.5)	17 (9.2)
Headache	15 (8.2)	10 (5.4)
Eczema	12 (6.5)	4 (2.2)
Dermatitis contact	11 (6.0)	6 (3.3)
Respiratory disorder	8 (4.3)	2 (1.1)
Rash	7 (3.8)	4 (2.2)
Glucose urine present	7 (3.8)	3 (1.6)
Upper respiratory tract inflammation	6 (3.3)	3 (1.6)

Hypersensitivity reactions and cases of anaphylaxis have been reported during post-approval use of RADICAVA IV infusion.[1]

Dosage and administration

Recommended dosage

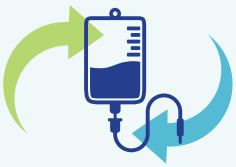
The recommended dosage of RADICAVA IV infusion is 60 mg of edaravone (two ampoules), which should be diluted with 100 mL of 0.9% sodium chloride for intravenous infusion.[1]

Method of administration

Administer RADICAVA IV infusion as an intravenous infusion over a 60-minute period.[1]

Dosing schedule for RADICAVA IV infusion

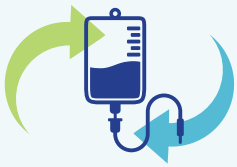
RADICAVA IV infusion is administered in structured cycles:[1]



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.[1]
The following cycle is to be started at 28 days after the first dosing date of the previous cycle.



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.[1]

Considerations for use[1]

- **Contraindications:** Contraindicated in individuals with a history of hypersensitivity to edaravone or any of the excipients found in RADICAVA IV infusion (refer to the full Product Information for a complete list).
- **Hypersensitivity reactions:** Monitor for reactions; RADICAVA IV infusion contains sodium bisulfite, which may cause allergic reactions, including anaphylaxis and life-threatening or less severe asthmatic episodes in susceptible individuals. The prevalence of sulfite sensitivity in the general population is unknown but is more common in people with asthma. If hypersensitivity reactions occur, discontinue RADICAVA IV infusion and provide standard care if needed.
- **Special populations:** No dosage adjustment is required for patients with hepatic impairment or mild to moderate renal impairment (estimated Glomerular Filtration Rate [eGFR] >30 mL/min/1.73 m^2).

Getting your patients started on RADICAVA IV infusion

Identify suitable patients

Clinical criteria:

- Diagnosis must have been made by a neurologist
- Symptoms not present for >2 years before therapy
- Predicted forced vital capacity (FVC) or slow vital capacity (SVC) ⩾80% within the last 2 months
- No assistance required with eating or ambulation
- ALSFRS-R score ⩾2 points on each item (available at: https://neurotoolkit.com/alsfrs-r/)
- No history of tracheostomy or respiratory failure

Obtain authority from the Pharmaceutical Benefits Scheme (PBS) for initial treatment

Authority can be requested:

Online via the PBS Authorities system at:
www.servicesaustralia.gov.au/HPOS or by scanning the QR code.

PBS codes
Public Hospital: 14805F
Private Hospital: 14804E

OR By phone through Services Australia on **1800 888 333**

Write prescription for initial treatment

Write out a script for **28 ampoules.**

Re-evaluate patient

Before obtaining PBS authority for continuing treatment, re-evaluate the patient to ensure they have not undergone a tracheostomy or experienced respiratory failure.

Obtain authority from the PBS for continuing treatment

As with initial treatment, authority* can be requested either online or by phone (see details above).
*PBS code: 14806G

Write prescription for continuing treatment

Write a script for **20 ampoules**, including **2 repeats** to be filled 28 days apart.

PBS INFORMATION: Authority Required. This product is listed on the PBS as a Section 100 item.
Refer to PBS Schedule for full authority information.

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.

Abbreviations: ALS, amyotrophic lateral sclerosis; **ALSFRS-R,** Revised Amyotrophic Lateral Sclerosis Functional Rating Scale; **CI,** confidence interval; **eGFR,** estimated glomerular filtration rate; **FVC,** forced vital capacity; **LOCF,** last observation carried forward; **LS,** least squares; **PBS,** Pharmaceutical Benefits Scheme; **SE,** standard error; **SVC,** slow vital capacity.

References: 1. RADICAVA® (edaravone) IV infusion Product Information. **2.** Edaravone (MCI-186) ALS 19 Study Group. *Lancet Neurol.* 2017;16(7):505–512.

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