

RADICAVA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using RADICAVA?

RADICAVA contains the active ingredient edaravone, RADICAVA is used to treat patients with amyotrophic lateral sclerosis (ALS). For more information, see Section [1. Why am I using RADICAVA?](#) in the full CMI.

2. What should I know before I use RADICAVA?

Do not use if you have ever had an allergic reaction to edaravone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RADICAVA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RADICAVA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is RADICAVA given?

RADICAVA is a concentrated solution for injection that must be diluted before use and will be prepared by a health care professional before it is given to you. RADICAVA will be given slowly into a vein as an infusion (drip) over 60 minutes.

Usually when you first start using RADICAVA, you will receive a dose each day for 14 days, followed by a 14-day drug free period. Following the first round of treatment, you will usually receive a dose each day for 10 days out of 14-day periods, followed by 14-day drug-free periods.

More instructions can be found in Section [4. How is RADICAVA given?](#) in the full CMI.

5. What should I know while using RADICAVA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse treating you that you are using RADICAVA.• Tell your doctor, pharmacist or nurse before using RADICAVA if you have a history of allergic reactions, especially if they are severe or if you are asthmatic.
Things you should not do	<ul style="list-style-type: none">• Do not use RADICAVA if you are allergic to edaravone, any of the ingredients in RADICAVA or sulfites.
Driving or using machines	<ul style="list-style-type: none">• RADICAVA is not expected to affect your ability to drive or operate machines.

For more information, see Section [5. What should I know while using RADICAVA?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of RADICAVA include bruising, walking problems and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

RADICAVA®

Active ingredient(s): *edaravone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RADICAVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RADICAVA.**

Where to find information in this leaflet:

- [1. Why am I using RADICAVA?](#)
- [2. What should I know before I use RADICAVA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is RADICAVA given?](#)
- [5. What should I know while using RADICAVA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RADICAVA?

RADICAVA contains the active ingredient edaravone which is understood to protect nerve cells from damage by removing harmful substances called free radicals.

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 disease onset.

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

ALS is a form of motor neurone disease where attacks of the nerve cells responsible for sending instructions to the muscles leads to muscle weakness, muscle wasting and paralysis.

2. What should I know before I use RADICAVA?

Warnings

Do not use RADICAVA if:

- you are allergic to edaravone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- are susceptible to hypersensitivity reactions (such as a skin rash or reddening).
- have ever suffered from symptoms of anaphylaxis (such as itchy skin or hives, low blood pressure or shortness of breath).
- are asthmatic.
- have severe kidney problems

RADICAVA contains sodium bisulfite, which may cause allergic reactions in susceptible people. Sensitivity to sulfite is more common in people with asthma. These allergic reactions include anaphylactic symptoms and life-threatening asthmatic episodes as well as less severe asthma symptoms.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is not known if RADICAVA will harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children and adolescents

RADICAVA should not be used in children and adolescents under the age of 18 years. The safety of RADICAVA and how well it works has not been studied in this age group.

Sodium content

Check with your doctor if you are following a low sodium diet. Each ampoule of RADICAVA contains 135 mg sodium chloride, 6.75 mg/mL (the main component of cooking salt). This should be taken into consideration by patients on a controlled sodium diet.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with RADICAVA and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RADICAVA.

4. How is RADICAVA given?

How much to use

Your doctor will decide what dose of RADICAVA you will receive. RADICAVA ampoules are a concentrated injection and must be diluted before use and is given slowly into a vein as an infusion.

The recommended dosage of RADICAVA is 60 mg of edaravone (two ampoules) diluted with 100 mL of 0.9% sodium chloride for infusion and administered as an intravenous infusion over a 60-minute period according to the following schedule:

- An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period.
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

RADICAVA is for single use in one patient only. Discard any residue.

To reduce microbiological hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2° - 8°C for not more than 24 hours.

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving the infusion of RADICAVA. The doctor or nurse looking after you will want to stop treatment if you are having an allergic reaction to the medicine.

If you use too much RADICAVA

RADICAVA is given to you under the supervision of a doctor or nurse, so it is unlikely you will receive too much. However, if you think that you have been given too much RADICAVA, tell your doctor or nurse immediately. You may need urgent medical attention.

5. What should I know while using RADICAVA?

Things you should do

Remind any doctor, nurse, dentist or pharmacist you visit that you are using RADICAVA.

Driving or using machines

RADICAVA is not expected to affect your ability to drive, cycle or use tools or machines.

Looking after your medicine

RADICAVA will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place, protected from light, where the temperature stays below 25°C.

Healthcare professionals will make sure that RADICAVA concentrated injection is not used after the 'EXP' date printed on the carton and that it is given to you as soon as the concentrated solution is diluted. They will also

visually inspect the solution prior to use and only clear solution, without particles will be used.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Changes to the way you walk or unsteadiness• Bruising• Fungal infections such as tinea• Headache• Difficulty breathing or shortness of breath• Skin rash, itchy skin, or skin inflammation• Sugar in the urine in test results	Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<p>Symptoms associated with hypersensitivity/allergic reactions:</p> <ul style="list-style-type: none">• Asthma attack (in people with asthma)• Shortness of breath, difficulty in breathing; wheezing, dizziness, fainting, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.	<p>Speak to your doctor or nurse if you notice any of these serious side effects.</p>

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RADICAVA contains

Active ingredient (main ingredient)	Edaravone
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Sodium bisulfite• Cysteine hydrochloride monohydrate• Sodium chloride• Sodium hydroxide• Phosphoric acid and• Water for injections
Potential allergens	Sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What RADICAVA looks like

RADICAVA 30 mg/20 mL concentrated solution for injection (AUST R 375455) is supplied as a clear, colourless, sterile solution in Type I clear glass ampoules and supplied in cartons containing 10 ampoules.

Pack size - 10 ampoules x 20 mL

Who distributes RADICAVA

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road,

Macquarie Park,

NSW 2113, Australia

RADICAVA® is a registered trademark of Tanabe Pharma Corporation.

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