Piramal Critical Care is a world leader in inhaled anesthetics, intrathecal therapy, and generic injectables, with a strong presence in more than 100 countries.

Backed by 25 years of quality, dependability, and growth, we are proud to offer a comprehensive U.S. product portfolio and bring you high-quality critical care drugs at affordable prices.

Edaravone Injection

For Intravenous Infusion Only

Available through the wholesaler or distributor of your choice:

2 Single-dose 30 mg/100 mL bags per carton, saleable unit NDC # 66794-259-64

WHOLESALER/DISTRIBUTOR	CATALOG NUMBER
ABC Wholesale	10291286
Cardinal	5927702
CuraScript SD	10005385
McKesson	2964682
Morris and Dickson	388181

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Indication and Important Safety Information you should know about Edaravone for Injection

DESCRIPTION:
Edaravone injection is supplied as a 30 mg/100 mL (0.3 mg/mL) clear, colorless, sterile solution for intravenous infusion in a single-dose polypropylene bag.

Therapeutic Indications: Edaravone injection is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Dosage and Administration: The recommended dosage of edaravone injection is an intravenous infusion of 60 mg administered over a 60-minute period.

Administer Edaravone injection 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.

Administration: Administer each 60 mg dose of Edaravone injection as two consecutive 30 mg intravenous infusion bags over a total of 60 minutes (infusion rate approximately 1 mg per minute [3.33 mL per minute]).

Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction. **[For additional information, please refer to the full prescribing information].**

CONTRAINDICATIONS:
Patients with a history of hypersensitivity to edaravone or any of the inactive ingredients in edaravone injection.

WARNINGS:
Hypersensitivity Reactions: Advise patients to seek immediate medical care. Sulfite Allergic Reactions: Edaravone injection contain sodium bisulfite, which may cause allergic type reactions, including anaphylactic symptoms and asthmatic episodes in susceptible people **[For additional information regarding, please refer to the full prescribing information].**

Drug Interactions: The pharmacokinetics of edaravone is not expected to be significantly affected by inhibitors of cytochrome P450 (CYP) enzymes, UGTs or major transporters. Concomitant oral administration of edaravone 120 mg (higher than the recommended dose of 105 mg for ORS) with sildenafil (CYP3A4 substrate), rosuvastatin (BCRP substrate), and furosemide (OAT3 substrate) did not produce any changes in Cmax and AUC of these drugs. **[For additional information regarding, please refer to the full prescribing information].**

Use in Specific Populations: Usage in Pregnancy: In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. The background risk for major birth defects and miscarriage in patients with ALS is unknown. **Usage in Children:** Safety and effectiveness of edaravone injection in pediatric patients have not been established. **Lactation:** There are no data on the presence of edaravone in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. **[For additional information regarding, please refer to the full prescribing information].**

ADVERSE REACTIONS:
Reported adverse reactions are as follows: Contusion, Gait disturbance, Headache, Reported adverse reactions are as follows: Contusion, Gait disturbance, Headache, Dermatitis, Eczema, Respiratory failure, respiratory disorder, hypoxia, Glycosuria, Tinea infection. **[For additional information, please refer to the full prescribing information]** [You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to www.fda.gov/medwatch or Piramal Critical Care, Inc. at 1-800-414-1901 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.]

STORAGE AND HANDLING:
Store Edaravone Injection at 20º to 25ºC (68º to 77ºF); excursions permitted from 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from light. Store in overwrapped package to protect from oxygen degradation until time of use. The oxygen indicator will turn blue or purple if the oxygen has exceeded acceptable levels. Once the overwrap package is opened, use within 24 hours. **[For additional information, please refer to the full prescribing information].**

HOW SUPPLIED:
Edaravone; NDC 66794-259-61 30 mg/100 mL (0.3 mg/mL) single-dose bag.

NDC 66794-259-64 2 bags per carton.

Ingredients: Active: Edaravone, **Inactive Ingredients:** L-cysteine hydrochloride hydrate, sodium bisulfite, sodium chloride, phosphoric acid, and sodium hydroxide.

- **Full prescribing information of Edaravone for Injection can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=19862ae9-d6e1-70e6-e063-6394a90ae749**
- **Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.**
- **You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.**

Piramal Critical Care

Piramal Critical Care, Inc.
3950 Schelden Circle
Bethlehem, PA 18017, USA
800-414-1901 • pcc.customerservice@piramal.com
piramalcriticalcare.us

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