EDAVON

For the use of a Neurologist or a Hospital or a Laboratory only

Abbreviated Prescribing information for EDAVON (Edaravone 1.5mg/mL Injection) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Edaravone scavenges free radicals and inhibits lipid peroxidation and thereby prevents oxidative damage to brain cells (vascular endothelial cells/nerve cells). **INDICATIONS**: Improvement of neurological symptoms, disorder of activities of daily living, and functional disorder associated with acute ischemic stroke. **DOSAGE AND ADMINISTRATION**: Edaravone injection is for intravenous infusion only. The usual adult dose is one ampoule (30 mg) diluted with an appropriate saline, which is administered over 30 minutes twice a day. The safety of edaravone has not been established in children. **CONTRAINDICATIONS**: Severe renal function disorder, history of hypersensitivity of drug or its any ingredient. **WARNINGS & PRECAUTIONS**: Aggravation of acute renal failure or renal impairment, severe liver disorder and/or disseminated intravascular coagulation (DIC). In the patients with infections or with severe disturbance of consciousness the risk/benefit evaluation should be carefully carried out before initiation of therapy. Should be monitored carefully, since scale lung injury with pyrexia, cough, dyspnea and chest X-ray abnormality may occur. rhabdomyolysis may occur. Caution is advised in patients wish cardiac disorder. The cardiac diseases may be aggravated and renal impairment may also occur. Caution required for rhabdomyolysis, thrombocytopenia or granulocytopenia and disseminated intravascular coagulation (DIG), cerebral embolism reoccurred or cerebral hemorrhage. **DRUG INTERACTIONS**: Precaution should be taken when edaravone is administered with cefazolin sodium, cefotiam hydrochloride, piperacillin sodium etc. The patients should be carefully monitored and renal function tests should be performed frequently in the concomitant use of the antibiotics, since renal impairment may be aggravated. **ADVERSE REACTIONS**: Acute renal failure, hepatic dysfunction, nephritic syndrome, hepatitis, jaundice, thrombocytopenia, granulocytopenia, disseminated intravascular coagulation (DIC), acute lung injury, rhabdomyolysis, shock, anaphylactic reaction (urticaria, decreased blood pressure and dyspnea), Redness, swelling, wheals, pruritus, Erythema (erythema Multiforme exsudativum, etc.), Decreased red blood cell count, increased white blood cell count, decreased white blood cell count, decreased hematocrit, Decreased hemoglobin, increased Platelet count, decreased platelet count, Injection site rash, Injection site redness, Increased BUN, increased serum uric acid, Proteinuria, hematuria, Increased creatinine, Nausea, Vomiting, feeling hot, Headache, increased blood pressure, increased serum cholesterol, Decreased serum cholesterol, increased triglyceride, increased CK (CPK), decreased CK (CPK), decreased Serum potassium, decreased Serum calcium.

MARKETED BY:

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(Additional information is available on request)