Summary of prescribing information for EDARABID injection

Active Ingredient: Each ml EDARABID contains: Edaravone JP 1.5 mg; 20 ml vial. **Indication:** For the improvement of neurological symptoms, disorder of activities of daily living, and functional disorder associated with acute ischaemic stroke. **Dosage:** Edaravone injection is for intravenous infusion only. Not for Bolus injection. Edaravone Injection should be diluted with normal saline before giving infusion. Patient is intravenously administered with 30 mg edaravone injection two times a day over 30 minutes. One time course of treatment should be less than 14 days. Patients should be intravenously administered with edaravone injection within 24 hours after onset of the disease. **Contraindications:** Patients with severe renal failure (there is a possibility of exacerbating renal failure if edaravone injection is administered). Patients who are allergic to edaravone. **Warning and precautions:** Hypersensitivity Reactions: Advise patients to seek immediate medical care. Sulfite Allergic Reactions: RADICAVA contains sodium bisulfite, which may cause allergic type reactions. **Pregnancy & Lactation:** Edaravone injection is contraindicated in women who are or may become pregnant (Whether the administration of edaravone injection during lactation is safe is still unknown). Edaravone injection should not be given to women during lactation. If women during lactation have to employ edaravone injection, the women should cease lactating when edaravone injection is administered (Animal experiment reports distribution of edaravone in milk). **Interaction:** When edaravone is used in combination with such antibiotics as cefazolin sodium, piperacillin sodium and cefotetan, there is a possibility of exacerbation of renal failure. Therefore, when edaravone is used in combination with these antibiotics, close observation of renal functions should be done. Edaravone must be diluted with physiological saline (When edaravone is diluted with liquid containing dextrose, concentration of edaravone will be reduced). Edaravone should not be intravenously administered in combination with high-octane liquid and amino acid preparation or through the same channel (Combined administration would reduce edaravone concentration).. Do not use edaravone in combination with antiepileptic drugs such as diazepam and phenytoin sodium (turbidity would occur). Do not use edaravone in combination with canrenoate potassium (turbidity would occur). **Adverse reactions:** common abnormal liver functions, rash, abnormal changes in laboratory test such as AST (aspartate aminotransferase) rise, ALT (alanine aminotransferase) rise. Severe reactions include: Acute renal failure, hepatic dysfunction and nephritic syndrome, hepatitis, jaundice, thrombocytopenia, granulocytopenia, disseminated intravascular coagulation (DIC), acute lung injury, rabdomylysis, shock; anaphylactoid reactions (urticaria, deceased blood pressure and dyspnea). **Overdose:** No data available.

Prepared on 24th Feb 2020.

It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com