

ABBREVIATED PRESCRIBING INFORMATION (ELAPRASE)

For the use of a registered medical practitioner or a hospital or a laboratory only
Abbreviated Prescribing Information
IDURSULFASE (r-DNA origin) 2mg/ml (Elaprase™) concentrate for solution for infusion

Mechanism of Action: Idursulfase is a purified form of the lysosomal enzyme iduronate-2- sulfatase, produced in a human cell line providing a human glycosylation profile, which is analogous to the naturally occurring enzyme. Idursulfase is secreted as a 525 amino acid glycoprotein and contains 8 N-linked glycosylation sites that are occupied by complex, hybrid, and high-mannose type oligosaccharide chains.

Indication and usage: Elaprase™ is indicated for the long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II).

Dosage administration: Elaprase™ is administered at a dose of 0.5 mg/kg body weight every week by intravenous infusion over a 3-hour period, which may be gradually reduced to 1 hour if no infusion- associated reactions are observed. Infusion at home may be considered for patients who have received several months of treatment in the clinic and who are tolerating their infusions well.

Interaction: No formal medicinal product interaction studies have been conducted with Idursulfase. Based on its metabolism in cellular lysosomes, Idursulfase would not be a candidate for cytochrome P450 mediated interactions.

Contraindications: Severe or life-threatening hypersensitivity to the active substance or to any of the excipients if hypersensitivity is not controllable.

Adverse reactions: Headache, Hypertension, flushing, Wheezing, dyspnoea, Abdominal pain, nausea, dyspepsia, diarrhoea, vomiting, Urticaria, rash, pruritus, Pyrexia, chest pain, infusion site swelling. Infusion related reaction, Dizziness, tremor, Cyanosis, arrhythmia, tachycardia, Hypotension, Hypoxia, tachypnoea, bronchospasm, cough, Swollen tongue, Erythema, Arthralgia, Face oedema, oedema peripheral, risk of anaphylactoid reaction.

Special population: There is no clinical experience in patients over 65 years of age. There is no clinical experience in patients with renal or hepatic insufficiency

Fertility, pregnancy and lactation: There are no data or limited amount of data from the use of Idursulfase in pregnant women. It is not known whether Idursulfase is excreted in human breast milk. No effects on male fertility were seen in reproductive studies in male rats.

Warning: To be sold by retail on the prescription of a "Registered Endocrinologist/Paediatrician/Medicine Specialist only"

Storage: Store in a refrigerator (2°C to 8°C). Do not freeze.

For more information refer full prescribing information

Imported & Marketed by: Takeda Biopharmaceuticals India Pvt. Ltd., 6th Floor, Tower - C, Building No.8, DLF Cyber City, DLF Phase-II, Gurgaon-122 002, Haryana, India

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