For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

FASTURTEC®

Rasburicase Injection

Abridged Prescribing Information

THERAPEUTIC CATEGORY
Detoxifying Agent for Antineoplastic Treatment

COMPOSITION
FASTURTEC® 1.5 mg/ml
Rasburicase 1.5 mg/ml powder and solvent for concentrate for solution for infusion.

THERAPEUTIC INDICATIONS
Treatment and prophylaxis of acute hyperuricaemia, in order to prevent acute renal failure, in patients with haematological malignancy with a high tumour burden and at risk of a rapid tumour lysis or shrinkage at initiation of chemotherapy.

DOSAGE AND ADMINISTRATION: Should be administered under the supervision of a physician trained in chemotherapy of haematological malignancies**.** Recommended dose is 0.20 mg/kg/day as a once daily 30 minute intravenous infusion in 50 ml of sodium chloride 9 mg/ml (0.9%) solution. Duration of treatment may be up to 7 days based upon acid uric levels and clinical judgment. No dose adjustment is necessary for renally or hepatically impaired patients. In paediatric patients, no adjustment is necessary; the recommended dose is 0.20 mg/kg/day.

SAFETY-RELATED INFORMATION
Contraindications: Hypersensitivity to uricases or any of the excipients. G6PD deficiency and other cellular metabolic disorders known to cause haemolytic anaemia.
Warnings: If any serious allergic or anaphylactic reaction occurs, treatment should immediately be discontinued and appropriate therapy initiated. Insufficient data are available on patients being retreated to recommend multiple treatment courses, at the present. Methemoglobinemia and hemolysis have been reported: treatment should be immediately discontinued and appropriate measures initiated.
Precautions: Caution should be used in patients with a history of atopic allergies.
Pregnancy and Lactation: Rasburicase should not be used during pregnancy or breast-feeding women.

ADVERSE REACTIONS: *Very common ≥ 10%*- vomiting, headache, nausea, fever, *Common ≥ 1 and <10%:* allergic reactions (mainly rashes and urticaria), cases of rhinitis, bronchospasm, hypotension, anaphylactic shock have been reported

For full prescribing information, please write to: Sanofi-Synthelabo (India) Private Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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