PEGALSA
(Pegaspargase)

Pegaspargase is an enzyme which consists of L Asparagine amidohydrolase that is covalently conjugated to monomethoxy polyethylene glycol (mPEG). L Asparaginase is a tetrameric enzyme that is produced endogenously by E coli and consists of identical 345 kDa subunits.

Dosage Form and Strength

Pegaspargase Solution for Injection 3750 IU/5 mL.

Clinical Pharmacology – Mechanism of Action

The mechanism of action of Pegaspargase is thought to be based on the selective killing of leukemic cells due to the depletion of plasma asparagine. Some leukemic cells are unable to synthesize asparagine due to a lack of asparagine synthetase and are dependent on an exogenous source of asparagine for survival Depletion of asparagine, which results from treatment with the enzyme L Asparaginase, kills the leukemic cells. Normal cells, however, are less affected by the depletion due to their ability to synthesize asparagine.

Indication

Pegaspargase is indicated as a component of a multi-agent chemotherapeutic regimen for the first line treatment of patients with Acute Lymphoblastic Leukemia (ALL).

Pegaspargase is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL and hypersensitivity to native forms of L Asparaginase.

Dosage and Administration

The recommended dose of Pegasparagase is 2,500 International Units intramuscularly or intravenously. Pegaspargase should be administered no more frequently than every 14 days.

When Pegaspargase is administered intramuscularly, the volume at a single injection site should be limited to 2 ml If the volume to be administered is greater than 2 ml, multiple injection sites should be used Pegaspargase does not contain a preservative.
Use only one dose per vial; discard unused product.

Storage and Handling

Pegaspargase (Pegaspargase Injection) is supplied as a sterile solution in Type-I single-use vial containing 3,750 International Units per 5 ml solution.

Store under refrigeration at 2 to 8°C and do not shake or freeze the product and protect it from light.

Packaging Information

Serious Allergic Reactions:
Patients should be informed of the possibility of allergic reactions, including anaphylaxis, and to report any swellings or difficulty breathing immediately.

Thrombosis:
Patients should be advised to immediately report any severe headache. Arm or leg swelling, acute shortness of breath, and chest pain also should be reported immediately.

Pancreatitis:
Patients should be advised to immediately report any severe abdominal pain.

Glucose Intolerance:
Patients should be advised to report excessive thirst or any increase in the volume or frequency of urination.

Manufactured By

M/s. Hetero Biopharma Limited,
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