ASPALSA
(L-Asparaginase)

L-Asparaginase for Injection contains the enzyme L-Asparaginase Amidohydrolase, type EC-2. Asparaginase is not absorbed from the GI Tract and hence must be administered IM or IV. The IM route maintains the efficacy and has not been shown to be less immunogenic. L-Asparaginase activity is expressed in terms of International Units according to the recommendation of the International Union of Biochemistry

Dosage Form

lyophilized powder for Injection (10,000 I.U/ Vial).

Clinical Pharmacology – Mechanism of Action

The mechanism of action of L-Asparaginase is thought to be based on selective killing of leukemic cells due to depletion of plasma asparaginase. Some leukemic cells are unable to synthesize asparaginase due to a lack of asparaginase synthetase and are dependent on an exogenous source of asparagine for survival. Depletion of asparaginase, 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 asparaginase.

Indication

L-Asparaginase for Injection is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL).

Dosage and Administration

L- Asparaginase should be prescribed and administered by physicians and healthcare personnel experienced in the use of antineoplastic products. It should only be given in a hospital setting where appropriate resuscitation equipment is available.

Storage and Handling

Keep Vials regenerated at 2-8°C (36-46°F). Protection from Light. Do not freeze.
L-Asparaginase for Injection does not contain a preservative. Store unused reconstituted solution at 2-8°C (36-46°F) and discard after eight hours or sooner if it becomes cloudy.

Packaging Information

L-Asparaginase for Injection is available in the following strength: 10,000 I.U/ Vial.
L-Asparaginase is supplied in flint glass vials containing 10,000 I.U of L-Asparaginase as a sterile, Lyophilized powder for Injection for reconstitution.

Reconstitution And Administration

FOR INTRAVENOUS USE

Reconstitute with sodium chloride injection. The volume recommended for reconstitution is 10ml for 10,000 I.U./ Vial. Dissolve without shaking. This solution may be used for direct intravenous administration. For administration by infusion, solutions should be diluted with isotonic solutions, Sodium Chloride injection or Dextrose Injection 5%.

FOR INSTRAMUSCULAR USE

When L-Asparaginase is administrated intramuscularly according to the schedule cited in the induction regimen, reconstitution is carried out by adding 2ml Sodium Chloride Injection to the 10,000 I.U./ Vial. The reconstituted solution contains 5,000 international units (IU)/ml

Manufactured By

M/s. Hetero Biopharma Limited,
Survey No. 458 (Part), TSIIC Formulation - SEZ,
Polepally Village, Jadcherla Mandal, Mahaboobnagar District – 509 301,
Telangana State, India.