Expansol IV Infusion

6% Hydroxyethyl Starch (130/0.4)
in 0.9% Sodium Chloride solution

Presentation
Expansol IV Infusion:

Each 100 ml solution contains:

Poly (O-2-hydroxyethyl) Starch BP 6.0 g
(Molar substitution: 0.37-0.43
Molecular weight: 110,000 – 150,000 daltons)

Sodium Chloride BP 0.9 g
(Na^+: 154 mmol/L
Cl^-: 154 mmol/L)

Water for Injections BP q.s.

Osmolality: 300±30 mOsm/kg

Description
Expansol (6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride IV infusion) is a clear to slightly opalescent, colorless to slightly yellow, sterile, non-pyrogenic, isotonic solution. The chemical name of Hydroxyethyl Starch is poly (O-2-hydroxyethyl) starch. Expansol contains Hydroxyethyl Starch in a colloidal solution which expands plasma volume when administered intravenously.

Indications and Usages
Hydroxyethyl Starch is indicated for the treatment and prophylaxis of hypovolemia in adults and children. It is not a substitute for red blood cells or coagulation factors in plasma.

Dosage and Administration
Hydroxyethyl Starch is administered by intravenous infusion only. The daily dose and rate of infusion depend on the patient's blood loss, on the maintenance or restoration of hemodynamics and on the hemodilution. Hydroxyethyl starchcan be administered repetitively over several days.
The initial 10 to 20 mL should be infused slowly, keeping the patient under close observation due to possible anaphylactoid reactions.

Adult Dose
Infusions up to 33 ml of Expansol per kg of body weight per day are most commonly used. There is a limited experience with infusions between 33 ml/kg/day and 50 ml/kg/day.

Pediatric Dose
Average 16 ± 9 ml of Expansol per kg of body weight per day. The dosage in children should be adapted to the individual patient colloid needs, taking into account the disease state, as well as the hemodynamic and hydration status.

Use in Pregnancy and Lactation
Pregnant women
There are no adequate and well-controlled studies in pregnant women. Hydroxyethyl starch should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactating mothers
It is not known whether this drug is excreted in human milk.

Precautions
Anaphylactoid Reactions
Anaphylactoid reactions (mild influenza-like symptoms, bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary edema) have been reported with solutions containing hydroxyethyl starch. If a hypersensitivity reaction occurs, administration of the drug should be discontinued immediately and the appropriate treatment and supportive measures should be undertaken until symptoms have resolved.

Renal Dysfunction
Avoid use in patients with pre-existing renal dysfunction. Discontinue use of Expansol at the first sign of renal injury. Continue to monitor renal function in hospitalized patients for at least 90 days.

Coagulopathy
Monitor the coagulation status of patients undergoing open heart surgery in association with cardiopulmonary bypass as excess bleeding has been reported with Hydroxyethyl Starch solutions in this population. Discontinue use of Expansol at the first sign of coagulopathy.

Fluid Equilibrium
Avoid fluid overload; adjust dosage in patients with cardiac or renal dysfunction. Fluid status and rate of infusion should be assessed regularly during treatment, especially in patients with cardiac insufficiency or severe kidney dysfunction.
In cases of severe dehydration, a crystalloid solution should be given first. Generally, sufficient fluid should be administered in order to avoid dehydration.

Monitoring: Laboratory Tests
Clinical evaluation and periodic laboratory determinations are necessary to monitor fluid balance, serum electrolyte concentrations, kidney function, acid-base balance, and coagulation parameters during prolonged parenteral therapy. Monitor liver function in patients receiving Hydroxyethyl Starch products.

Contraindication
• Do not use Hydroxyethyl Starch products, including Expansol, in critically ill adult patients, including patients with sepsis, due to increased risk of mortality and renal replacement therapy.
• Do not use Hydroxyethyl Starch products, including Expansol, in patients with severe liver disease.
• Do not use Hydroxyethyl Starch products, including Expansolin patients with known hypersensitivity to Hydroxyethyl Starch.
• Do not use Hydroxyethyl Starch products in clinical conditions with volume overload.
• Do not use Hydroxyethyl Starch products in patients with pre-existing coagulation or bleeding disorders.
• Do not use Hydroxyethyl Starch products in patients with renal failure with oliguria or anuria.
• Do not use Hydroxyethyl Starch products in patients receiving dialysis treatment.
• Do not use Hydroxyethyl Starch products in patients with severe hypernatremia or severe hyperchloremia.
• Do not use Hydroxyethyl Starch poducts in patients with intracranial bleeding.

Overdose
Over dosage can lead to overloading of the circulatory system (e.g., pulmonary edema). In this case, the infusion should be stopped immediately and if necessary, a diuretic should be administered.

Drug Interactions
No interactions with other drugs or nutritional products are known.

Side Effects
Most common adverse reactions (incidence >1%) are pruritus, elevated serum amylase, hemodilution. Anaphylactoid/hypersensitivity reactions can occur.

Storage
Store at room temperature. Do not freeze.

Commercial Pack
Expansol IV Infusion: Each box contains one glass bottle of 500 ml solution, one infusion set and one hanger.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

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