Plasmafil®

Hydroxyethyl Starch in Sodium Chloride Solution

Description
Plasmafil® is a sterile solution containing 6% Hydroxyethyl Starch (130/0.4) in isotonic Sodium Chloride solution. It is a clear to slightly opalescent, colorless to slightly yellow, sterile, non-pyrogenic, isotonic solution for intravenous administration.

Composition
Plasmafil® 500 ml IV Infusion: Each 100 ml contains: Hydroxyethyl Starch (130/0.4) BP 6.0 gm, Sodium Chloride BP 0.9 gm and Water for injection BP q.s. to 100 ml.

Indications
Plasmafil® 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 & administration
Plasmafil® 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 (dilution effect). It can 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:
Up to 50 ml of **Plasmafil®** per kg of body weight per day (equivalent to 3 g Hydroxyethyl Starch and 7.7 mEq Sodium per kg of body weight). This dose is equivalent to 3500 ml of 6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride for a 70 kg patient.
Pediatric Dose:
The dosage of **Plasmafil®** 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.
For newborns to infants (<2 years), a mean dose of 16±9 ml/kg of body weight per day.
For the children from 2-12 years of age a mean dose of 36±11 ml/kg of body weight per day. The dose in adolescents >12 is the same as the adult dose.

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

Side effects
The most common adverse reactions after administration of **Plasmafil®** is pruritus, itching, elevation of serum amylase interference with the diagnosis of pancreatitis and dilutional effects that may result in decreased levels of coagulation factors and other plasma proteins and in a decrease of hematocrit.
Anaphylactoid reactions occur rarely in administration of **Plasmafil®**. Disturbances of blood coagulation beyond dilution effects can occur rarely in <0.1% depending on the dosage with the administration of **Plasmafil®**.

Use in pregnancy
Pregnancy category C. It has been shown to cause embryocidal or other adverse effects in rats and rabbits when given in doses 1.7 times the human dose. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use during lactation
It is not known whether Hydroxyethyl Starch (HES) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when it is administered to a nursing woman.

Warnings and 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 this product 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 this product 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 or whenever the patient's condition warrants such evaluation. Monitor liver function in patients receiving Hydroxyethyl Starch products.

Drug interactions
No interactions of Hydroxyethyl Starch (HES) with other drugs or nutritional products are known or have been reported to date. However, mixing Hydroxyethyl Starch (HES) with other drugs should be avoided.

Caution
Do not use if the solution is turbid, contains particles or after expiry date. Discard any unused portion.

Storage
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Plasmafil® 500 ml IV Infusion: 500 ml sterile solution in clear glass bottle.

00-01

Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.