"PLASMEX® 6% W/V STERILE SOLUTION FOR INFUSION" [500ML PLASTIC BOTTLE]

Summary of Product Characteristics

PLASMEX

6% Hydroxyethyl starch (130/0.42) in isotonic sodium chloride solution.

Qualitative and quantitative composition:

1000 ml contain:

Active constituents:

Poly(O-2-Hydroxyethyl)starch (Degree of substitution 0.38 – 0.45) (Average molecular weight Mw : 130,000)	**60.00 g**
Sodium chloride	**9.00 g**

Na^+ 154 mmol/L

CL^- 154 mmol/L

Theoretical osmolarity 308 mOsmol/L

Therapeutical indications:

1). **Therapy and prophylaxis of volume deficiency (hypovolaemia) and shock in connection with: surgery (haemorrhagic shock), injuries (trumatic shock), infections (septic shock), burns (burn shock),**
2). **Therapeutic haemodilution (isovolaemic haemodilution).**

Summary of Product Characteristics (Continued)

Contra-indications:

- Fluid overload (hyperhydration) including pulmonary oedema.
- Renal failure with oliguria or anuria.
- Patients receiving dialysis treatment.
- Intracranial bleeding.
- Severe hypernatremia or severe hyperchloremia.
- Known hypersensitivity to hydroxyethyl starches.

Special warnings and precautions for use:

Fluid overload caused by overdose should be avoided in general. Particularly for patients with cardiac insufficiency or severe kidney dysfunctions the increased risk of hyperhydration must be taken into consideration; posology must be adapted.
In cases of severe dehydration a crystalloid solution should first be given.

Particular care must be taken in patients with severe liver disease or severe bleeding disorders, e.g. severe cases of von Willebrand's disease.

It is important to supply sufficient fluid and to regularly monitor kidney function and fluid balance.

Serum electrolytes should be monitored.
There are no data available on the use of Plasmex in children. Plasmex may be given to children only after careful risk/benefit evaluation.

Regarding the occurrence of anaphylactoid reactions please refer to section" Undesirable effects".

Pregnancy and lactation:

For Plasmex no clinical data on exposed pregnancies are currently available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or postnatal development. No evidence of teratogenicity was seen. Plasmex should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

There are currently no clinical data available on the use of Plasmex in lactating women.

Summary of Product Characteristics (Continued)

Interactions with other medications:

No interactions with other drugs or nutritional products are known to date. Please refer to section" Undesirable effects" concerning the concentration of serum amylase which can rise during administration of hydroxyethyl starch and can interfere with the diagnosis of pancreatitis.

Posology and method of administration:

For intravenous infusion:

The initial 10-20 ml are to be infused slowly, keeping the patient under close observation (due to possible anaphylactoid reactions).

The daily dose and rate of infusion depend on the patient's blood loss, on the maintenance or restoration of haemodynamics and on the haemodilution (dilution effect).
The daily dose is up to 50 ml / Kg BW / day ≅ 3 gm HES / Kg BW / day
≅ 3.750 ml / 75 Kg BW / day

Rates of infusion: a) in hemorrhagic shock
up to 33 ml / kg BW / hour
0.55 ml / Kg BW / minute
(≅ 2,500 ml / 75 Kg BW / hour).
(≅ 42 ml / 75 Kg BW / minute).
b) in septic and burn shock lower rates of infusion
c) in children under 10 years of age
do not exceed 25 ml/Kg BW/hour (≅ 0.42 ml/Kg BW / minute).

The duration of treatment depends on the duration and extent of hypovolaemia, the haemodynamics and on the haemodilution. There is currently no clinical experience for application lasting several days.

Overdose (symptoms, emergency procedure, antidotes):

As with all volume substitutes, overdose can lead to overloading of the circulatory system (e.g. pulmonary oedema). IN this case the infusion should be stopped immediately and if necessary, a diuretic should be administered.

Undesirable effects:

Medicinal products containing hydroxyethyl starch may lead to anaphylactoid reactions (hypersensitivity, mild influenza-like symptoms, bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary oedema) in very rare cases.

In the event of an intolerance reaction occurring the infusion should be discontinued immediately and the appropriate emergency medical treatment initiated.

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Summary of Product Characteristics (Continued)

The concentration of serum amylase can rise during administration of hydroxyethyl starch and can interfere with the diagnosis of pancreatitis.
Pruritus (itching) after prolonged administration of high dosages is a known undesirable effect of hydroxyethyl starches.

At high dosages the dilution effects may result in a corresponding dilution of blood components such as coagulation factors and other plasma proteins and in a decrease of hematocrit.
With the administration of hydroxyethyl starches disturbances of blood coagulation can occur depending on the dosage.

***Remarks*:**

The mixing with other drugs should be avoided. If, in exceptional cases, a mixture with other drugs is required, care should be taken with the compatibility (clouding or precipitation), hygienic injection and a good admixture.

Sheril El-Behady
Registration Head

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