

Infukoll 6% solution for infusion

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Infukoll® 6 % solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml contains:

Poly (O-2-hydroxyethyl)starch	60.0 g
(Molar substitution	0.45-0.55)
(Average molecular weight:	200 000 Da)
Sodium chloride	9.00 g
Na ⁺	154 mmol
Cl ⁻	154 mmol
Theoretical osmolarity	309 mosmol/l
pH	5.0-7.0

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion. Clear, colourless, aqueous solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment and prevention of hypovolaemia and shock. Normovolaemic haemodilution.

4.2 Posology and method of administration

HES must be administered intravenously.

Total dosage, duration and rate of infusion will depend upon the amount of blood lost and/or the haemodynamic status and general clinical condition of the patient. Dosage will need to be adjusted as necessary by monitoring the usual circulatory parameters e.g. blood pressure.

The risk of circulatory overload by too rapid rate of infusion or inappropriately large doses must be borne in mind.

Due to the risk for occurrence of an anaphylactic reaction, the first 10 ml - 20 ml of Infukoll® 6 % should be infused slowly and under careful observation of the patient.

Maximum infusion rate:

The maximum rate of infusion should be adjusted to the clinical situation. Patients with acute haemorrhagic shock: Up to 20 ml/kg bodyweight/hour (equivalent to 0.33 ml/kg BW/min). In life-threatening situations: 500 ml as a rapid infusion (under pressure). The rates of infusion selected for perioperative indications and for burns and septic shock patients will usually be lower.

Maximum daily dosage:

A maximum daily dosage of 2 g/kg bodyweight/day of hydroxyethyl starch (HES) should not be exceeded. This corresponds to 33 ml/kg bodyweight/day of the 6 % solution (approximately 2,500 ml/day in a person of 75 kg). Experience of treatment of more than 1-2 days is limited. In cases of longer treatment the daily doses have generally been lower. An increasing risk of undesirable effects with high cumulative doses (see section 4.8) should be considered.

Children:

There are no data concerning usage of Infukoll® 6 % in children. Administration to children should only be managed after careful benefit/risk assessment.

Further information:

Patients with primarily interstitial fluid losses must firstly be treated with crystalloids. After infusion of HES controls of serum electrolytes and fluid balance are required. Electrolytes must be administered as required. In all patients adequate fluid supply is essential. Renal function must be monitored during treatment (control of serum creatinine).

Because of the possibility of allergic (anaphylactic/anaphylactoid) reactions, appropriate monitoring of patients is necessary. (See section 4.4)

4.3 Contraindications

- Known hypersensitivity to hydroxyethyl starch
- Hypervolaemia
- Hyper-hydration (e.g. water intoxication)
- Hyperchloraemia (or hypernatraemia)
- Congestive cardiac failure
- Pulmonary oedema
- Renal failure, with oliguria and anuria
- Cerebral haemorrhage
- Severe blood coagulation disorders
- Severe hepatic impairment

4.4 Special warning and precautions for use

Particular caution should be exercised and the dosage adjusted as appropriate in patients who have impaired renal clearance since this is the principal way in which Infukoll® 6 % is eliminated. In these patients especially, adequate fluid supply is essential. Renal function, including serum creatinine, must be monitored both before and during treatment. Monitoring of the serum electrolytes and fluid balance is necessary.

Circulatory overload: The possibility of circulatory overload should be considered. Caution should be exercised in patients at risk of pulmonary oedema and/or congestive cardiac failure; and severely impaired renal function. Because of the possibility of allergic (anaphylactic/ anaphylactoid) reactions, appropriate monitoring of patients is necessary. (See section 4.4). In case of an allergic reaction, the infusion must be stopped immediately and appropriate treatment given.

Like all colloidal plasma substitutes, Infukoll® 6 % produces coagulation factor dilution. In particular, there is a change in Factor VIII activity, which is, however, temporary and reversible, and, in the absence of other blood coagulation disorders, has no clinical significance. Infukoll® 6 % should be used with caution in patients with preexisting blood coagulation disorders, impaired hepatic function or haemorrhagic diathesis.

Haematocrit may be decreased and plasma proteins diluted by infusion of large volumes of Infukoll® 6 %. Administration of packed red cells, fresh frozen plasma, platelets or full blood should also be considered if excessive dilution occurs.

Samples for blood group determination must be obtained before HES administration because the product may interfere with the tests and cause false positive answers for irregular agglutinins.

Elevated serum alpha amylase concentrations about three times the upper limit of normal may be observed temporarily following administration of HES solutions which may interfere with the diagnosis of pancreatitis. This elevated alpha amylase activity is due to the formation of an enzyme-substrate complex of amylase and HES subject to slow renal elimination and therefore must not be considered diagnostic of impaired pancreatic function. (See sections 4.8 and 5.2).

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of heparin or oral anticoagulants may increase coagulation time.

4.6 Pregnancy and lactation

For Infukoll® 6 % no clinical data on exposed pregnancies are available. No reproductive toxicological studies in animals with Infukoll® 6 % have been performed, but studies with similar hydroxyethyl starch products have caused vaginal bleeding and embryoletality during repeated treatment of test animals. Harmful embryo effects may occur with HES associated anaphylactic reactions in the pregnant mother.

