HAEMACCEL®

ACTIVE INGREDIENT: POLYGELINE

3,5% COLLOIDAL INFUSION SOLUTION FOR VOLUME SUBSTITUTION

COMPOSITION

1000 ml contain: Polypeptides of degraded gelatin (origin: bovine bone), cross-linked via urea bridges 35g (equivalent of 6.3g of nitrogen)

	mmol	g
chloride ions	145	5.14
potassium ions	5.1	0.20
calcium ions	6.25	0.25
sodium ions	145	3.33

Traces of phosphate ions and sulphate ions, plus anionic polypeptides up to the isoionic point.

Water for injections: ad 1000 ml

PHYSICO-CHEMICAL DATA:

Mean molecular weight	30000 Dalton*
Relative viscosity (35°C)	1.7-1.8
pH of the infusion solution	7.3+ 0.3
Gel point	below +3°C

* determined using modern analytical techniques

PRESENTATION AND CONTENTS BY WEIGHT, VOLUME OR NUMBER OF ITEMS.

Clinic pack of 1 plastic infusion bottle.

SUBSTANCE OR INDICATION CATEGORY

Infusion solutions, volume replacement.

INDICATIONS

Haemaccel is a plasma substitute for volume replacement used to correct or avert circulatory insufficiency due to plasma/blood volume deficiency, either absolute (e.g. resulting from bleeding) or relative (e.g.resulting from a shift in plasma volume between the circulatory compartments).

Haemaccel is applied in the following areas:

• Hypovolaemic shock

• Loss of blood and plasma (e.g. due to trauma, burns, autologous blood or plasma donation before an operation)

• For filling the heart-lung machine. In addition Haemaccel can be used as a carrier solution for various drugs.

CONTRAINDICATIONS

Known hypersensitivity to constituents of the preparation. Existing severe allergic reactions. In the following cases, Haemaccel is indicated to a restricted extent only.

If the physician considers the infusion necessary, it should be given taking special precautions: All conditions in which an increase in intravascular (blood vessel) volume and its consequences (e.g. increased stroke volume, elevated blood pressure), or an increase in interstitial fluid volume or haemodilution could represent a particular risk for the patient. Examples of such conditions are: congestive heart failure, hypertension, oesophageal varices, pulmonary oedema, haemorrhagic diathesis, renal and post-renal anuria. In all patients at an increased risk of histamine release (e.g. persons with allergic/allergoid reactions and patients with a history of histamine response). In the latter cases Haemaccel may be given only after taking appropriate prophylactic steps (see Measures of precaution for administration). Use of the preparation in pregnant women and nursing mothers is not contraindicated. Generally, however, particular care should be exercised when fluid or volume replacements are administered during or immediately after pregnancy.

MEASURES OF PRECAUTION FOR ADMINISTRATION

For physiological reasons Haemaccel should not be infused in the cold state, like all infusion solutions. Infuse clear solutions only. Reactions caused by histamine release can be avoided by the prophylactic use of H1 and H2 receptor antagonists (e.g. Dimetinden 0.1mg/kg of body weight i.v. and Cimetidin 5mg/kg of body weight iv.).

For technical reasons there is a residual air volume in the container. Thus, pressure infusions with the plastic infusion bottle must be carried out under controlled conditions only, as the risk of an air embolism can not be excluded.

INTERACTIONS WITH OTHER AGENTS

In the case of patients receiving cardiac glycosides, the synergistic effect of the calcium in Haemaccel should be taken into account.

DOSAGE INSTRUCTION, MODE AND DURATION OF ADMINISTRATION

Dosage, unless otherwise prescribed: Dosage and infusion rate are to be adjusted to the individual situation and are determined among other factors by the usual circulatory parameters (e.g. blood pressure).

The degree of efficacy and the duration of the effect achieved depend on the infusion volume, the infusion rate and the existing volume deficit. For healthy adults the following volumes are considered appropriate: blood or plasma loss.

shock prophylaxis	500-1500 ml
volume deficiency shock	up to 2000 ml
in emergencies	volume as required

The blood pressure is the parameter of reference. The above volumes may be even higher, provided that the essential elements of the blood are maintained above the critical limit of dilution and that hypervolaemia and hyperhydration are avoided. Generally at the latest the administration of red cell concentrate or coagulation factors must be considered when the haematocrit falls below 25% by volume. Note that in the case of babies, infants and elderly persons such patients have inadequate reserves of protein.

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MODE OF ADMINISTRATION

Haemaccel is a ready-for-use solution to be infused by the intravenous route. The rate and duration of the infusion depend on the needs of the patient. The infusion speed is to be adjusted in accordance with the monitored blood pressure values. The drip rate can be calculated using the following formula:

e.g.: 500 ml to be infused in 1hour:

$$\frac{500}{4x1(h)} = 125 \text{ drips per minute}$$

In emergencies it is possible to administer Haemaccel as a rapid infusion (e.g. 500ml in 5 to 15min).

SIDE EFFECTS

If you develop side-effects which are not mentioned in this package insert, please inform your doctor or pharmacist. During or after the infusion of plasma substitutes, transient skin reactions (urticaria, wheals), hypotension, tachycardia, bradycardia, nausea/vomiting, dyspnoea, increases in temperature and/or chills may occasionally occur.

Rare cases of severe hypersensitivity reactions reaching as far as life-threatening shock have been observed. Here, the treatment required depends on the nature and severity of the side-effect. If side effects occur the infusion should be discontinued at once. If necessary, treatment should be given as follows: Mild reactions: administer antihistamines. Severe reactions: if appropriate immediately inject catecholamines slowly i.v., plus high doses of corticosteroids slowly i.v., volume replacement, oxygen. Histamine release has been shown to be the cause of anaphylactoid side-effects associated with infusions of Haemaccel. Histamine-induced reactions can be encouraged by rapid infusion. Furthermore, the above-described reactions may occur as a result of the cumulative effect of several histamine-releasing drugs (e.g. anaesthetics, muscle relaxants, analgetics, ganglia blockers and anticholinergic drugs).

STORAGE AND STABILITY

Haemaccel should be stored at +2°C to +25°C. The solution must not be used after the date of expiry given on the pack and container. If Haemaccel is stored at above +25°C the stated expiry date has to be reduced by 2 years. Once an infusion bottle has been opened, any unused contents are to be discarded.

Store out of reach of children!

ADDITIONAL INFORMATION

The preparation contains no preservative. Freezing and thawing do not result in a change in its physico-chemical properties. Histochemical, radiochemical and histological studies have shown that Haemaccel is not stored in the RES. Disturbances of organ functions have not been observed even at high dosages. In patients with intact renal function polygeline is normally fully excreted 48 hours after the end of the infusion. If, for example in dialysis patients, the polygeline cannot be excreted adequately it will be degraded by endogenous proteases. Infusion of haemaccel leads to haemodilution and thus lowers the viscosity of the blood.

This can result in an improvement of microcirculation. Administration of Haemaccel does not induce antibody formation. Haemaccel does not lead to a substance-specific impairment of coagulation or platelet function. However, if large amounts are infused, haemodilutional effects on the coagulation potential occur. Blood-grouping tests are not affected by polygeline.

NOTES

Due to the raised calcium content of Haemaccel, the serum calcium concentrations may be found to be slightly elevated for a temporary period-especially when large amounts of Haemaccel are administered by rapid infusion. So far no reports have been received of cases involving clinical signs of hypercalcaemia resulting from an infusion of Haemaccel. In case of simultaneous administration of Haemaccel and blood, anticoagulated with citrate, into separate venous accesses no adverse reaction is to be expected; recalcification of the citrated blood due to the calcium ion content in Haemaccel can only occur when Haemaccel is mixed with it or if subsequent infusions are given using the same venous access. Heparinised blood, however, can be mixed with Haemaccel. Taking sterile precautions, Haemaccel can be mixed with the usual infusion solutions (saline, glucose, Ringer's solution, etc.) as well as with cardiovascular drugs, corticosteroids, muscle relaxants, barbiturates, vitamins, streptokinase, urokinase, antibiotics of the penicillin series and cefotaxime, provided that these are soluble in water. The infusion of Haemaccel may result in a temporary increase in the erythrocyte sedimentation rate.

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This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists