SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Haemaccel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Haemaccel contains 35 g Polygeline as active ingredient in 1,000 ml.

Excipient(s) with known effect
Each 500ml vial contains 4.25g sodium chloride.
Each 500ml vial contains 0.20g potassium chloride.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. As a plasma volume substitute in the initial treatment of hypovolaemic shock due to:
   a) Haemorrhage (visible or concealed)
   b) Burns, peritonitis, pancreatitis, crush injuries
2. Fluid replacement in plasma exchange
3. Extra-corporeal circulation
4. Isolated organ perfusion
5. As a carrier solution for insulin

4.2 Posology and method of administration

Posology

Haemaccel should be administered intravenously in a volume approximately equal to the estimated blood loss.
See section 6.6. for Special precautions for disposal and other Handling.

Infusion rate:
The rate of infusion is determined by the condition of the patient. Normally, 500 ml will be infused in not less than 60 minutes but in emergencies Haemaccel can be rapidly infused. Losses of up to 25 % of the blood volume can be replaced by Haemaccel alone.

Hypovolaemic shock:
500 -1,000 ml Haemaccel should be infused intravenously initially.
Up to 1,500 ml blood loss can be replaced entirely by Haemaccel. For between 1,500 ml and 4,000 ml blood loss, fluid replacement should be with equal volumes of Haemaccel and blood given separately (see Pharmaceutical Precautions). For losses over 4,000 ml, the separate infusion should be in the ratio of two parts blood to one part Haemaccel. The Haematocrit should not be allowed to fall below 25 %.

Burns:
It is suggested that at least 1 ml Haemaccel be infused per kg of body weight. Multiplied by the % of body surface burned for each 24 hours for two days, e.g. if a 70 kg person has burns covering 10 % of body surface, then the dosage of Haemaccel should be at least 1 (ml) x 70 (kg) x 10 (%) = 700 ml/24 hours. Additional crystalloid solutions should be given to cover the normal fluid loss, i.e. about 2,000 ml per 24 hours. In severe burns additional protein and vitamin therapy may be required. The volume of colloid and crystalloid given should be varied according to the clinical response of the patient, the urine volume, its specific gravity and osmolality etc.

Plasma exchange:
Haemaccel should be given either alone or in combination with other replacement fluids in a volume adequate to replace the plasma removed.
Up to 2 litres have been given as sole replacement fluid.

Method of administration
Intravenous infusion.

4.3 Contraindications

Haemaccel is contra-indicated in patients with a known hypersensitivity to constituents of the preparation and/or patients with existing anaphylactoid reactions.

4.4 Special warnings and precautions for use

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 volume and its consequences (e.g. increased stroke volume, elevated blood pressure), or an increase in interstitial fluid volume, or haemodilution could represent a special 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. allergic persons and patients with a history of histamine response; also patients who in the previous 7 days have received a drug which releases histamine). In the latter cases, Haemaccelmay be given only after taking appropriate prophylactic steps. Reactions caused by histamine release can be avoided by the prophylactic use of H1 and H2 receptor antagonists.
Inappropriate rapid administration of Haemaccel, especially to normovolaemic patients may cause the release of vasoactive substances. The exact mechanism of this histamine release has not been clearly defined.

Haemaccel contains sodium chloride and potassium chloride:
Haemaccel contains 4.25g sodium chloride & 0.20g potassium chloride per 500ml.

This medicinal product contains approximately 0.1847mmol sodium in each 500ml vial. This should be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains approximately 0.005mmol potassium in each 500ml vial. This should be taken into consideration by patients on a controlled potassium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Haemaccel contains calcium ions and caution should be observed in patients being treated with cardiac glycosides. Haemaccel may be mixed with other infusion solutions (e.g. saline, dextrose, Ringer's solution etc.) or with heparinised blood. Sterility must be maintained. Compatible water-soluble drugs may be infused in Haemaccel, e.g. insulin, streptokinase etc. Any additive should be injected into the bottle through a small hole located next to the pull-ring.

4.6 Fertility, Pregnancy and lactation

Haemorrhage around the time of childbirth or blood loss during other obstetric or gynaecological procedures may necessitate plasma volume replacement. Haemaccel has been used for many years for the initial treatment in such cases without apparent ill consequence.
If plasma volume replacement is needed during pregnancy, Haemaccel may be used if blood is not available.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

During or after the infusion of volume-expanding solutions, transient urticarial skin reactions (wheals), hypotension, tachycardia, bradycardia, nausea/vomiting, dyspnoea, increases in temperature and/or shivering may occasionally occur.

Rare cases of severe hypersensitivity reactions including shock have been observed. Treatment will depend on the nature and severity of the reaction. Mild reactions: administer corticosteroids and antihistamines.

In the event of anaphylactic shock, the infusion should be discontinued and adrenalin (5-10 ml of 1:10,000 by slow i.v. injection or 0.5 -1.0 ml of 1:1,000 by i.m./s.c. injection) should immediately be given. Administration of adrenalin should be repeated every 15 minutes until improvement occurs. Circulatory collapse requires volume replacement, preferably monitored by a central venous pressure line. Large volumes of electrolyte solution may be necessary because, in severe anaphylactic shock, plasma loss may constitute up to 40 % of the plasma volume. A slow i.v. injection of an H1 antagonist such as 10 - 20 mg chlorpheniramine may be given.

Histamine release has been shown to be a cause of anaphylactic side-effects associated with infusions of Haemaccel.

These reactions may occur as a result of the cumulative effect of several histamine-releasing drugs (e.g. anaesthetics, muscle relaxants, analgesics, ganglia blockers and anticholinergic drugs).

Due to the 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.

The infusion of Haemaccel may result in a temporary increase in the erythrocyte sedimentation rate.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to

report any
suspected adverse reactions via
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Haemaccel is a gelatin derivative with a mean molecular weight of 30,000 Dalton. It is iso-oncotic with plasma and has a viscosity and pH similar to plasma. It has very little pharmacological action and does not interfere with cross matching or blood typing tests.

5.2 Pharmacokinetic properties

Haemaccel has a mean half-life of about 5 hours. About 74 % is excreted via the kidneys four days after administration.

It is metabolised into smaller peptides and amino acids by proteolytic enzymes.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride, Ph. Eur.	4.25 g;
Potassium Chloride, Ph. Eur.	0.20 g;
Calcium Chloride Ph. Eur.	0.466 g;
Water for Injections, Ph. Eur.	to 500 ml.

6.2 Incompatibilities

Citrated blood should NOT be mixed with Haemaccel since clotting of the blood may occur due to the presence of calcium ions in Haemaccel. However,

citrated blood may be infused before or after Haemaccel provided that there is adequate flushing of the infusion set.

6.3 Shelf life

2 years

6.4 Special precautions for storage

None

6.5 Nature and contents of container

500 ml Polypropylene bottles.
Insocap (Polypropylene cap with elastomer liner)

6.6 Special precautions for disposal

In common with all intravenous infusion, Haemaccel should, if possible, be warmed to body temperature before use.
However, in emergencies, it may be infused at ambient temperature. 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 cannot be excluded.

7 MARKETING AUTHORISATION HOLDER

Piramal Critical Care Limited,

Suite 4, Ground Floor

Heathrow Boulevard - East Wing,

280 Bath Road, West Drayton, UB7 0DQ,

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 37071/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th January 2005

10 DATE OF REVISION OF THE TEXT

02/08/2019