HAEMACCEL
ACTIVE INGREDIENT : POLYGELINE

Piramal | Healthcare
Piramal Healthcare UK Limited
Whalton Road, Morpeth
Northumberland, NE 61 3YA,
United Kingdom

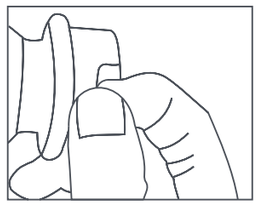
AHM40063UK XXXXXX

5.3. Preclinical safety data
None.
6.0 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 and other handlings
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.
7.0 MARKETING AUTHORISATION HOLDER
Piramal Healthcare UK Limited, Whalton Road, Morpeth, Northumberland, NE 61 3YA, United Kingdom
8.0 MARKETING AUTHORISATION NUMBER(S)
PL 29595/0001
9.0 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
15th January 2005
10.0 DATE OF REVISION OF THE TEXT
May 2016

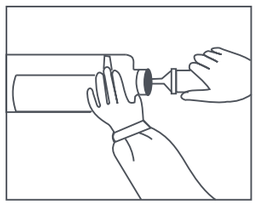
OPENING THE BOTTLE AND INSERTION OF THE GIVING SET

01 Disinfect the bottle top.

02 Disinfect the surface of the plastic cap.
Pull gently the aluminium seal from the side.
Peel the aluminium seal to insert the giving set.



03 Push the giving set firmly through the bung until penetration occurs, and fluid is seen to be flowing. If plastic-tip-ped giving sets are used, a twisting motion may be helpful. Alternatively a sterile needle may be used to produce an initial aperture.



N.B. Failure to penetrate the bung may be due to a blunt giving set. If additional bottles need to be used, a fresh giving set should be used.

SUMMARY OF PRODUCT CHARACTERISTICS

1.0 NAME OF THE MEDICINAL PRODUCT
Haemaccel
2.0 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
3.0 PHARMACEUTICAL FORM
Solution for infusion
4.0 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 Instructions for Use/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. Interactions with other medical 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 at: Website: www.mhra.gov.uk/yellowcard
4.9. Overdose
Not applicable.
5.0 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.

Package leaflet: Information for the patient

HAEMACCEL

(Polygeline)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Haemaccel is and what it is used for Haemaccel contains the active substance polygeline.
Haemaccel is one of a group of medicines called "plasma substitutes". It is used to provide fluid to a patient in a number of situations, for example: a) To replace fluid which has been lost due to bleeding (e.g. haemorrhage, child birth or during gynaecological procedures), burns or inflammation. b) To provide fluid to an organ during an operation on that organ. c) To provide fluid for an insulin injection. Ask your doctor or nurse for more information if you have any questions.
2. What you need to know before you use Haemaccel : Do not use Haemaccel
- If you are allergic to Haemaccel or any of the ingredients of this medicine (listed in section 6)
- If you have any allergies and/or are you currently experiencing any allergic reactions(s)
- If you have difficulty breathing
- If you have any kidney disease
- If you are intolerant to injections
- If you have a tendency to bleed or do you have any inherited bleeding disorder (e.g. haemorrhagic diathesis)
- If you have any heart condition
- If you have hypertension (high blood pressure)
- If you have any varices (enlarged veins)
- If you suffer from oedema (swelling due to fluid retention)

If you think any of the above statements applies to you, then discuss the situation with your doctor or nurse.
Warnings and precautions : Talk to your doctor or nurse before using Haemaccel.
In the following cases, Haemaccel is indicated to a restricted extent, 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, Haemaccel may 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.

Other medicines and Haemaccel : Tell your doctor if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor if you are taking or using : cardiac glyco-sides to treat a heart condition (e.g. digoxin or digitoxin); anaesthetics; muscle relaxants; pain killers; drugs to treat hypotension (e.g. trimetaphan camsylate); or anticholinergics.
Pregnancy, breast-feeding and fertility : If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. 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.
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This medicinal product contains approximately 0.005mmol potassium in each 500ml vial. This should be taken into consideration by pateints on a controlled potassium diet.
3. How to use Haemaccel : Haemaccel will usually be given to you by intravenous infusion (drip). The dose given will depend on your condition. A typical infusion rate will be 500 ml of Haemaccel over 1 hour. However, Haemaccel may be given to you more rapidly in an emergency situation.
4. Possible side effects : Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects to Haemaccel may include:
- Hypotension (e.g. dizziness on standing)
- Skin rash (e.g. wheals)
- Hypercalcaemia (increased levels of calcium in the blood)
- Increased temperature and/or shivering
- Shortness of breath or breathing difficulties.
- Nausea and/or vomiting
- A change in heart beat (e.g. heart murmur or flutter)

In rare cases, you may experience an allergic reaction to Haemaccel, resulting in shock. If this happens, your doctor or nurse will give you appropriate treatment to remedy this. If you experience any of the above side effects or any other unusual or unexpected symptoms, then tell your doctor or nurse.
Reporting of side effects : If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.
5. How to store Haemaccel : You will not normally be asked to store your medicine as it will be given to you by the doctor. There are no special storage instructions for Haemaccel. Haemaccel contains no preservatives; therefore any unused fluid should be discarded once the bottle has been opened. Do not use this medicine after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month. Remember this medicine is for you. Only a doctor can prescribe it to you. Keep this medicine out of the sight and reach of children. This leaflet does not contain all the information about your medicine. If you have any question or are not sure about anything, ask your doctor or nurse, who have access to additional information. This leaflet only applies to Haemaccel.
6. Contents of the pack and other information : What Haemaccel contains
- The active substance is polygeline.
- The other ingredient(s) are sodium chloride, potassium chloride, calcium chloride and water for injection

What Haemaccel looks like and contents of the pack : Haemaccel comes as a 500 ml solution in plastic bottles.
Marketing Authorisation Holder and Manufacturer : Piramal Healthcare UK Limited, Whalton Road, Morpeth, Northumberland, NE 61 3YA, United Kingdom
This Leaflet was last revised in May 2016.

160 mm x 289 mm / Front Side

160 mm x 289 mm / Back Side

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