1. TRADE NAME OF THE MEDICINAL PRODUCT
Haemaccel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Haemaccel contains 35 g Polygeline as active ingredient in 1,000 ml.

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, pancreatitis, crush injuries
   c) Fluid replacement in plasma exchange
   d) Extra-corporeal circulation
   e) Isolated organ perfusion
   f) As a carrier solution for insulin

4.2 Posology and Method of Administration

Route of Administration

1. As a plasma volume substitute in the initial treatment of hypovolaemic shock due to:
   a) Haemorrhage (visible or concealed)
   b) Burns, pancreatitis, crush injuries

2. Fluid replacement in plasma exchange

3. Extra-corporeal circulation

4. Isolated organ perfusion

5. As a carrier solution for insulin

4.3 Contra-Indications
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, 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 vasactive substances. The exact mechanism of this histamine release has not been clearly defined.

4.5 Interactions with other Medicaments 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 Pregnancy and Lactation
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 (wheels), 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 adrenaline (5–10 ml of 1:1,000, 0.5–1.0 ml of 1:1,000) should be immediately given. Administration of adrenaline 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. anasthesetics, 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 hypercalcemia resulting from an infusion of Haemaccel. The infusion of Haemaccel may result in a temporary increase in the erythrocyte sedimentation rate.

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 4.5 hours. About 76 % is excreted via the kidneys four days after administration.

5.3 Pre-Clinical Safety Data
None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
Sodium Chloride, Ph. Eur. 8.5g; Potassium Chloride, Ph. Eur. 0.39g; Calcium Chloride Ph. Eur. 0.7g; Water for Injections, Ph. Eur. to 1.0 Litre.

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.

6.6 Instruction for Use/Handling
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 slowly only, as the risk of an air embolism cannot be excluded.

7. MARKETING AUTHORISATION HOLDER
Piramal Healthcare UK Limited
Whalton Road, Morpeth,
Northumberland NE61 3YA
United Kingdom

8. MARKETING AUTHORISATION NUMBER
PI 29595/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
15th January 2005

10. DATE OF (PARTIAL) REVISION OF THE TEXT
February 2012