Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gentran 40 (Dextran 40 Intravenous Infusion BP 10% w/v in Sodium Chloride Intravenous Infusion BP 0.9% w/v).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml contains:

Dextran 40 (Dextran 40 for Injection)	100	g
Sodium Chloride	9	g

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.

A clear, colourless, sterile, aqueous solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the treatment of hypovolaemic shock.

Prophylaxis of thromboembolic episodes in surgery.

As a diluent in the pump oxygenator during extra-corporeal circulation.

To improve blood flow and tissue function in burns and conditions associated with local ischaemia.

4.2 Posology and method of administration

Dosage
The dosage is dependent upon the age, weight and clinical condition of the patient.

Hypovolaemic Shock
Adults
Usual dose is 500 to 1500ml, depending on individual response. This dose should not be exceeded except in unusual circumstances.

Paediatric Patients
Children 10ml/kg - Babies 5ml/kg.

Prophylaxis of thromboembolic episodes
500 -1000ml daily commencing on day of surgery and continuing for 2-5 days post operatively.

As diluent in pump oxygenator
10 to 20ml/kg. The dextran concentration should never exceed 3%.

To improve blood flow and tissue function in burns/ischaemia
Usual dose is 500ml prior to surgery and 500ml during surgery. Dosage depends on individual patient's circumstances and response.

Administration
Intravenous.

4.3 Contraindications

Use in patients hypersensitive to dextrans.

Use in patients with severe congestive heart failure or cardiac decompensation, thrombocytopenia or in those with anuria or severe oliguria.

4.4 Special warnings and precautions for use

Overloading of the circulation with ensuing cardiac distress and pulmonary oedema may occur with this product. It should therefore be given with caution to patients vulnerable to vascular overloading e.g. congestive cardiac failure and renal disease.

Excessive use of this product may lead to a hemorrhagic diathesis and prolonged bleeding, due to interference with platelet function and plasma clotting factors. It should not be used inconjunction with heparin.

Presence of dextran in blood may interfere with blood group typing, when enzymatic methods are used.

This product may give rise to renal impairment resulting from tubular damage or more rarely acute glumerulo-nephritis. The danger of the former is increased in the dehydrated/oliguric state, and the product should not be used if diuresis is less than 1500ml/24 hour.

This solution is hyperosmotic and dehydration should be corrected before or at least during dextran infusions.

Dextran infusions produce a progressive dilution of oxygen carrying capacity, coagulation factors and plasma proteins. Deficiencies should be corrected and fluid and electrolyte balance maintained.

Discontinue if adverse reaction occurs.

4.5 Interaction with other medicinal products and other forms of interaction

Not specified.

4.6 Pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician. Anaphylactic reactions in the mother have been reported to cause anoxic brain damage which resulted in the death of the foetus in a number of cases.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

This product may give rise to severe anaphylactoid reactions, usually in the first few minutes of infusion, particularly in patients with a history of asthma or allergy. Patients should be carefully supervised and appropriate resusitatory measures should be immediately available. Less severe side effects such as urticaria, nausea, vomiting, fever, joint pains and flushing may occur.

4.9 Overdose

Not specified.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Low molecular weight polysaccharide, 70% of which is excreted in urine in 24 hours. Slow metabolism of the remainder to carbon dioxide and water takes place in the liver.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Sodium hydroxide
Hydrochloric acid, concentrated

6.2 Incompatibilities

Do not use additives unless compatibility is known.

Do not administer blood through the same giving set.

6.3 Shelf Life

Unopened: 2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A clear, collapsible, PVC container effectively sealed, available in 500 ml or 1000 ml volumes. The container is sealed in a high density polyethylene or polypropylene overpouch.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Do not use unless solution is clear and the container is undamaged.

Discard any unused portion.

Do not reconnect partially used bags.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.,
Caxton Way,
Thetford,
Norfolk,
IP24 3SE,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 0167/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 1st April 1983

Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

March 2007