

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dextran 70 Intravenous Infusion BP 6.0% w/v in Glucose Intravenous Infusion BP 5.0% w/v.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000ml contains:

Dextran 70 /Dextran 70 for Injection	60.0	g
Anhydrous glucose	50.0	g
<u>or</u>		
Glucose Monohydrate	55.0	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

Treatment of early stages of venous thrombosis.

As a plasma volume expander in treatment of hypovolaemic shock, haemorrhagic traumatic burns.

Prophylaxis of postoperative thromboembolism.

4.2 Posology and method of administration

Dosage

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

As plasma volume expander

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

For prophylaxis of post operative thromboembolism/treatment of early stages of venous thrombosis

The usual dose is 500ml before surgery, if necessary followed by 500ml daily on every other day.

Administration

Solution is for administration by intravenous infusion only.

4.3 Contraindications

Dextran 70 is contraindicated:

- In patients with severe congestive heart failure or cardiac decompensation, thrombocytopenia or in those with anuria or severe oliguria
- In patients hypersensitive to dextrans.

4.4 Special warnings and precautions for use

Less severe side effects, such as urticaria, nausea, vomiting, fever, joint pains and flushing may occur.

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 eg. congestive cardiac failure and renal disease.

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

The presence of dextran in blood may interfere with blood group typing when carried out by enzymatic methods.

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

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

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

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 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

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 resuscitatory measures should be immediately available.

4.9 Overdose

Not specified.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Polysaccharide of which 50% of an intravenous dose is excreted in urine within 24 hours. The remainder is slowly metabolised in liver to carbon dioxide and water.

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 transfuse blood through the same giving set.

Do not use additives unless compatibility is known.

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. Each container is sealed into 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 the 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.,
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Norfolk,
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8 MARKETING AUTHORISATION NUMBER

PA 0167/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

March 2007