

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Gentran 70 (Dextran 70 Intravenous Infusion BP 6.0% w/v in Sodium Chloride Intravenous Infusion BP 0.9% w/v).

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml contains:

Dextran 70 (Dextran 70 for Injection)	60	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

Dextran 70 is used for early fluid replacement or for plasma volume expansion in the adjunctive treatment of certain types of shock, or in impending shock when whole blood or fluid products are not available, including shock resulting from burns, surgery, haemorrhage or trauma, in which circulating volume deficit is present. It should not replace other forms of therapy known to be of value in the treatment of shock.

##### 4.2 Posology and method of administration

###### Dosage

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

###### *Hypovolaemic shock*

The usual dose is 500 ml to 1000 ml initially, followed by 500 ml later if necessary, depending on the individual response. This dose should not be exceeded except in unusual circumstances. Recommended dosage in children is 10 ml/kg and in babies 5ml/kg.

###### Administration

The solution is for administration by intravenous infusion only.

##### 4.3 Contraindications

Dextran 70 Intravenous Infusion BP is contraindicated in the presence of thrombocytopenia, severe congestive heart failure, renal disease with severe oliguria or anuria, where there is known hypersensitivity to Dextran, and in patients receiving heparin or low molecular weight heparins (see below).

## 4.4 Special warnings and precautions for use

Dextran 70 Intravenous Infusion BP may give rise to 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.

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

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

Dextran 70 may give rise to renal impairment resulting from tubular damage or more rarely acute glomerulo-nephritis. The danger of the former is increased in the dehydrated/oliguric state. Following administration of 500 ml, if no increase in urinary output is observed, the infusion should be discontinued until adequate diuresis is established.

### Precautions

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

The presence of Dextran in blood may interfere with blood group typing, when enzymatic methods are used.

The solution is hyperosmotic and dehydration should be corrected before or at least during Dextran infusion.

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.

## 4.5 Interaction with other medicinal products and other forms of interaction

Do not use with heparin or low molecular weight heparins (see Section 4.4 above).

Dextran 70 Intravenous Infusion BP has a tendency to crystallise when stored at low temperatures. Storage should therefore be at a constant temperature not exceeding 25°C. If the solution is cloudy or contains sediment it should not be used.

As with all parenterals, compatibilities should be checked when additives are used. Always discontinue dosage if an adverse reaction occurs.

Thorough and careful mixing of any additives is mandatory. Avoid storage of such solutions.

## 4.6 Pregnancy and lactation

Safe use of Dextran 70 during pregnancy or lactation has not been established and should not be used unless the potential benefits outweigh the possible risks to the foetus or neonate.

Anaphylactic reactions (see section 4.8 Undesirable Effects) during pregnancy have been reported to cause anoxic brain damage which has resulted in death of the foetus in some cases.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

Mild urticarial reactions, rarely severe anaphylactoid reactions, increase in viscosity and specific gravity of urine, reversible tubular vacuolisation, increased serum levels of aspartate or alanine transaminases and occasionally transient acidosis.

As with any prolonged infusion, venous irritation and thrombophlebitis may occur at the injection site.

## 4.9 Overdose

In the event of an accidental over infusion, treatment should temporarily be either discontinued or rate of infusion decreased significantly, depending on extent of over infusion. The patient should be observed for symptoms and signs of cardiorespiratory decompensation, hepatic and renal functions. Fluid and electrolyte balance should be carefully monitored together with any evidence of bleeding diathesis. Other symptomatic and supportive measures should be provided.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Colloidal solution which holds about 20 ml of water per gram of dextran.

## 5.2 Pharmacokinetic properties

When administered to a patient in shock, Dextran 70 may increase blood volume, blood pressure, pulse pressure, capillary perfusion, central venous pressure, urinary output and decrease heart rate, peripheral resistance and mean transit time. About 70% of the Dextran 70 administered is excreted in the urine within 24 hours of administration. The remainder is partly excreted in the faeces and partly metabolised.

## 5.3 Preclinical safety data

Not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Sodium hydroxide  
Hydrochloric acid, concentrated  
Water for injections

## 6.2 Incompatibilities

Do not administer 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. 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 Limited,  
Caxton Way,  
Thetford,  
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IP24 3SE,  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 0167/027/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorization: 1<sup>st</sup> April 1983

Date of last renewal: 1<sup>st</sup> April 2003

## **10 DATE OF REVISION OF THE TEXT**

March 2007