

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion 5%

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Polyfusor D has the following composition:

Name	Specification Reference	w/v
Glucose Monohydrate for Parenteral Use BP	EP	5.5
<i>(Equivalent to Anhydrous Glucose BP</i>	<i>EP</i>	<i>5.0)</i>

### 3 PHARMACEUTICAL FORM

Intravenous infusion

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

The produce is indicated in simple dehydration, carbohydrate depletion, and hypoglycaemic coma. It can also be used to provide a temporary increase in blood volume in haemorrhage and shock.

#### 4.2 Posology and method of administration

##### Adults and Children

The rate of administration and volume infused will depend upon the requirements of the individual patient and judgement of the physician.

##### Elderly

Care should be taken to avoid circulatory overload, particularly in patients with cardiac and renal insufficiency.

For intravenous infusion.

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. Glucose Intravenous Infusion 5% may become extremely hypotonic after administration due to glucose metabolization in the body (see sections 4.4, 4.5 and 4.8).

### **4.3 Contraindications**

Diabetes, except as a treatment for hypoglycaemia. The intravenous infusion of glucose solutions may also be hazardous in, patients with impaired hepatic or renal function.

### **4.4 Special warnings and precautions for use**

The infusion of these solutions should not be rapid or very prolonged large volumes of these solutions given too quickly may cause water intoxication; infusion over a long period can cause dehydration.

The label states: Do not use unless solution is clear and free from particles.

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

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

No clinically significant drug interactions known.

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.: Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

#### **4.6 Fertility, pregnancy and lactation**

The safety of this product during pregnancy and lactation has not been assessed. But its use during these periods is not considered to constitute a hazard.

Glucose Intravenous Infusion 5% should be administered with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

#### **4.7 Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

Thrombosis of the chosen vein is always a possibility with intravenous infusion.

Tabulated list of adverse reactions
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System Organ Class	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutrition disorders	Hospital Acquired Hyponatraemia**	Not known
Nervous system disorders	Hyponatraemic encephalopathy**	Not known

\*\* Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

#### 4.9 Overdose

Overdosage may lead to fluid overload and hyperglycaemia. Fluid overload may need to be treated with a diuretic and hyperglycaemia with insulin.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Glucose is a monosaccharide, which provides a source of energy.

### 5.2 Pharmacokinetic properties

Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with the release of energy. All body cells are capable of oxidising glucose and it forms the principal source of energy in cellular metabolism.

### 5.3 Preclinical safety data

None stated

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Name	Specification Reference	% w/v
Water for Injections in bulk BP	EP	To 100
Sodium Hydroxide BP	BP	QS
Hydrochloric Acid BP	EP	QS

### 6.2 Incompatibilities

Incompatible with blood, frusemide, hydralazine cyanocobalamin, kanamycin sulphate, novobiocin sodium or warfarin sodium

**6.3 Shelf life**

Semi-rigid, cylindrical neutral polythene container with a 'Twist-off' seal: 36 months.

Polyethylene bottle with cap and administration/addition points: 36 months.

**6.4 Special precautions for storage**

Store at 2° to 25°C

**6.5. NATURE AND CONTENTS OF CONTAINER**

Sealed semi-rigid, cylindrical neutral polythene container with a 'Twist-off' seal at one end and a ring tab at the opposite end

Or

Polyethylene bottle with a cap with an administration point and an addition point (KabiPac)

The container holds 50, 100, 250, 500 or 1000ml

**6.6 Special precautions for disposal and other handling**

Do not dilute before use

Use standard sterile peritoneal dialysis equipment

**7 MARKETING AUTHORISATION HOLDER**

Fresenius Kabi Limited  
Cestrian Court  
Eastgate Way  
Manor Park  
Runcorn  
Cheshire  
WA7 1NT

**8 MARKETING AUTHORISATION NUMBER**

PL 08828/0056

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

05/06/1989 / 12/04/2005

**10 DATE OF REVISION OF THE TEXT**

11/04/2019