



## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **PRODUCT SUMMARY**

#### **1. NAME OF THE MEDICINAL PRODUCT**

Glucose Intravenous Infusion BP 50% w/v.

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains 50% w/v of Glucose EP.

#### **3. PHARMACEUTICAL FORM**

Sterile Injection.

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

Glucose 50% is hypertonic and provides a source of calories in a minimal volume of water. Glucose 50% is frequently used in both adults and children to restore blood glucose concentrations in the treatment of hypoglycaemia resulting from insulin excess or from other causes.

Glucose 50% may be used to provide temporary relief from the symptoms of cerebral oedema and from hypoglycaemic coma. Hyperosmotic Glucose with or without insulin may correct hyperkalaemia in renal failure and also some forms of hyponatraemia.

##### **4.2 Posology and method of administration**

Glucose 50% must be administered by the intravenous route; it must not be administered by subcutaneous or intramuscular route. Except in the emergency treatment of severe hypoglycaemia, Glucose 50% should be administered via a central vein after appropriate dilution. When used for the emergency treatment of hypoglycaemia, Glucose 50% may be administered slowly into a peripheral vein at a rate not greater than 3mls per minute.

Dosage of Glucose depends on the age, weight, clinical condition, the fluid, electrolyte and acid base balance of the patient. For the treatment of hypoglycaemia resulting from insulin excess or other

causes in adults (including the elderly) and children, the usual dose is as follows:

20-50ml of Glucose 50% administered slowly intravenously. This represents 3mls per minute.

Repeated doses and supportive therapy may be required in some cases.

#### **4.3 Contraindications**

Glucose 50% is contraindicated in patients with the glucose – galactose malabsorption syndrome. Hypertonic Glucose solutions are contraindicated in patients with anuria or intraspinal or intracranial haemorrhage and in patients with delirium tremens if such patients are already dehydrated. Hypertonic Glucose solutions are also contraindicated in patients with diabetic coma or known allergy to corn or corn products.

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

Glucose solutions should be used with caution in patients with overt or known sub-clinical diabetes mellitus or with carbohydrate intolerance for any reason. Intravenous administration of Glucose may cause fluid and/or solute overload, resulting in a dilution of serum electrolytes, overhydration, congestive conditions or pulmonary oedema.

Intravenous administration of Glucose may result in hypokalaemia, hypophosphataemia and hypomagnesaemia. Rapid administration of hypertonic glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome; patients should be observed for signs of mental confusion and loss of consciousness, especially those patients with chronic uraemia or carbohydrate intolerance.

#### **4.5 Interactions with other medicinal products and other forms of interactions**

None known.

#### **4.6 Pregnancy and lactation**

As with any other drug the use of Glucose 50% injection should be used in the pregnant female at the discretion of the physician, where benefit to the mother outweighs any possible adverse effects on the foetus.

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

None known.

#### **4.8 Undesirable effects**

Administration of a hypertonic solution of Glucose may cause venous thrombosis or phlebitis extending from the site of injection. Local pain and vein irritation may occur. Hyperglycaemia and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated this can lead to dehydration, hyperosmolar coma and death.

#### **4.9 Overdose**

Overdose of Glucose 50% may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.

In the event of overdose of Glucose 50% it may be necessary to administer appropriate doses of insulin.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Not applicable.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

No further information other than that which is included in the Summary of Product Characteristics.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Hydrochloric Acid  
Water for Injections Ph. Eur.

#### **6.2 Incompatibilities**

Glucose solutions which do not contain electrolytes, should not be administered concomitantly with blood through the same infusion set, because of the possibilities of agglomeration.

#### **6.3 Shelf life**

36 months.

**6.4 Special precautions for storage**

Store at less than 25°C.

**6.5 Nature and contents of container**

20ml type I clear glass ampoules, packed in cardboard cartons to contain 10 ampoules x 20ml.

50ml type II clear glass vials, packed in cardboard cartons to contain 10 or 25 vials x 50ml.

**6.6 Instructions for use, handling and disposal**

Use as directed by the physician.

**ADMINISTRATIVE DATA**

**7. MARKETING AUTHORISATION HOLDER**

hameln pharmaceuticals Ltd  
Gloucester  
UK

**8. MARKETING AUTHORISATION NUMBER**

PL 1502/0005R

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

4th December 1989/ 24th August 2001

**10. DATE OF (PARTIAL) REVISION OF TEXT**

September 2007