SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Solution for Infusion

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains <STRENGTH> w/v of glucose

For the full list of excipients, see section 6.1.

<REGARDING THE APPROVAL>

1. PHARMACEUTICAL FORM

Solution for Infusion

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Glucose <STRENGTH> is hypertonic and provides a source of calories in a minimal volume of water. Glucose <STRENGTH> 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 <STRENGTH> 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.

* 1. Posology and method of administration

Glucose <STRENGTH> 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 <STRENGTH> should be administered via a central vein after appropriate dilution. When used for the emergency treatment of hypoglycaemia, Glucose <STRENGTH> 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 <STRENGTH> administered slowly intravenously. This represents 3mls per minute.

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

* 1. Contraindications

Glucose <STRENGTH> is contraindicated in patients with the glucose – galactose malabsorption syndrome.

Hypertonic Glucose solutions are contraindicated in patients with anuria or intraspinal or intracranial haemorrhage, or ischaemic stroke 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.

* 1. Special warnings and precautions for use

Hypertonic solutions of Glucose should be administered via a large central vein to minimise damage at the site of injection (see section 4.2 Posology).

Glucose solutions should be used with caution in patients with overt or known sub- clinical diabetes mellitus, carbohydrate intolerance for any reason, severe under- nutrition, thiamine deficiency, hypophosphataemia, haemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.

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.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored.

Changed in fluid balance, electrolyte concentrations and acid-base balance should be evaluated during prolonged therapy. Intravenous administration of Glucose may result in hypokalaemia, hypophosphataemia and hypomagnesaemia.

* 1. Interaction with other medicinal products and other forms of interaction

None known.

* 1. Fertility, pregnancy and lactation

Intravenous glucose may result in foetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate. Infusions of glucose administered during Caesarean section and labour should not exceed 5-10g glucose/hour.

* 1. Effects on ability to drive and use machines

None known.

* 1. Undesirable effects

*Metabolic and nutrition disorders:*

Hyperglycaemia, hypokalaemia, hypophosphataemia, hypomagnesaemia, fluid and electrolyte imbalance.

Hyperglycaemia (possibly indicated by mental confusion or loss of consciousness) and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated hyperglycaemia can lead to dehydration, hyperosmolar coma and death.

The administration of glucose without adequate levels of thiamine may precipitate overt deficiency states e.g. Wernicke’s encephalopathy. Sodium retention, oedema, pulmonary oedema and congestive heart failure may be induced in patients with severe under-nutrition.

*Nervous system:*

See Metabolic and nutrition disorders.

*General and administration site disorders:*

Pain at the injection site, vein irritation, venous thrombosis, phlebitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC

* 1. Overdose

Overdose of Glucose <STRENGTH> may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.

In the event of overdose of Glucose <STRENGTH> it may be necessary to administer appropriate doses of insulin.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, Carbohydrates, ATC code: B05BA03

The metabolism of glucose is an energy source for the body.

* 1. Pharmacokinetic properties

Glucose is rapidly metabolised into carbon dioxide and water.

* 1. Preclinical safety data

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

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. 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.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>