

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucose 5% in half strength Hartmann's, solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name	% w/v
Sodium Chloride BP for Injections	0.3
Potassium Chloride BP	0.02
Calcium Chloride Dihydrate	0.014
Glucose Monohydrate for Parenteral Use BP	5.5
(Equivalent to Anhydrous Glucose BP	5.0)
Lactic Acid BP	
Sodium Hydroxide BP	
Lactic Acid BP and Sodium Hydroxide BP are added in the form of 2M Sodium Lactate Solution or a Premade 50% Sodium Lactate Solution to produce a concentration of Sodium Lactate of	0.159

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of dehydration with acidosis associated with carbohydrate deficiency, when a low concentration of sodium is indicated, as in paediatric dehydration and hypernatraemic states.

4.2 Posology and method of administration

Posology

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.

Method of administration

Intravenous use.

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 5% in half strength Hartmann's, solution for infusion may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5 and 4.8).

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Patients with severe salt and water retention and hyperkalaemic states.

Patients with severe liver damage and those unable to convert lactate to bicarbonate.

4.4 Special warnings and precautions for use

Caution is necessary when considering the use of this solution in patients with cardiac failure, hypertension, impaired renal function and peripheral or pulmonary oedema.

The label states: Do not use unless solution is 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

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 solution during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard.

Glucose 5% in half strength Hartmann's, solution for infusion 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 relevant.

4.8 Undesirable effects

Rapid administration can cause oedema and convulsions.

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

Tabulated list of adverse reactions		
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).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows the continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google play or Apple App store.

4.9 Overdose

Overdosage should not occur. Over administration can be treated with intravenous injection of a diuretic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium chloride, sodium chloride and calcium chloride provide essential ions to maintain the intracellular/extracellular milieu.

Sodium lactate is used as a source of bicarbonate ions, which will correct acid-base balance

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

5.2 Pharmacokinetic properties

Sodium lactate is metabolised in the liver to sodium bicarbonate.

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

Not available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Hydrochloric acid

Sodium hydroxide

6.2 Incompatibilities

Incompatible with novobiocin, oxytetracycline, sodium bicarbonate, sodium calcium edetate and sulphadiazine sodium.

Because of the nature of the plastic material of the Steriflex bag (PVC), this solution should not be used as a vehicle for the administration of drugs, which may be sorbed to the surface of the bag to varying and significant degrees.

6.3 Shelf life

500 & 1000ml PVC Bags - 24 months.

500 & 1000ml Polyolefin Bags – 36 months.

6.4 Special precautions for storage

Store between 2°C - 25°C.

6.5 Nature and contents of container

The container is a flexible 500 or 1000ml bag made of medical grade PVC.

- a) A hermetically sealed polythene bag.
- b) A rectangular pouch consisting of polyamide/polythene composite
- c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Opening the overwrap:

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution:

Position the roller clamp of the giving-set to just below the drip chamber and close.

Hold the base of the giving set port firmly and grip the wings of the twist of tab. Twist to remove the protective cover. Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection. Prime the set in accordance with the manufacturer's instructions.

7 MARKETING AUTHORISATION HOLDER

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WA7 1NT

8 MARKETING AUTHORISATION NUMBER(S)

PL 8828/0089.

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