SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.45% and Glucose 5% Intravenous Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 0.45% and Glucose 5% Intravenous Infusion has the following composition:

Name	Specification Reference	%w/v
Sodium Chloride for Injections	EP	0.45
Glucose Monohydrate for Parenteral use	EP	5.5
(Equivalent to Anhydrous Glucose		5.0

For the full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Intravenous fluid

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

An isotonic solution for maintenance treatment of dehydration with carbohydrate loss.

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
A reduced volume and rate of infusion may be necessary to avoid circulatory overload, particularly in patients with cardiac or 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. Sodium Chloride 0.45% and Glucose 5% Intravenous Infusion 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

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1
Patients with impaired renal or cardiac function. The intravenous infusion of glucose containing solutions may be hazardous in patients with impaired liver function.
Sodium Chloride 0.45% and Glucose 5% Intravenous Infusion is not suitable for the treatment of insulin coma.

4.4 Special warnings and precautions for use

Glucose-Saline solutions should not be administered rapidly for prolonged periods particularly in infants and the elderly. In potassium deficient patients administration of saline will increase potassium loss, so that if it is given, potassium supplements should also be given.
Restrict intake in impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema, toxaemia of pregnancy. This guidance is particularly relevant for isotonic and hypertonic forms.
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 metabolization (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 Interactions 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. No clinically significant drug interactions known.

4.6 Fertility, pregnancy and lactation

Sodium Chloride 0.45% and Glucose 5% Intravenous Infusion should be administrated 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).
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.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Tabulated list of adverse reactions		
System Organ Class	System Organ Class	System Organ Class
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).

Thrombosis of the chosen vein is always a possibility with intravenous infusion. If Infusion is protracted then another vein should be selected after 12-24 hours.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose may lead to fluid overload and electrolyte imbalance and possibly hyperglycaemia.

Hyperglycaemia may need to be treated with insulin and fluid overload with a diuretic.

Electrolyte disturbances may need to be treated with either sodium-free or sodium containing fluids.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes with Carbohydrates, ATC code: B05BB02

Sodium chloride provides essential sodium and chloride ions to maintain the osmotic tension of the extracellular fluid and tissues.

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

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name
Water for Injection in Bulk
Hydrochloric Acid – for pH adjustment
Sodium Hydroxide – for pH adjustment

6.2 Incompatibilities

Incompatibilities Amiodarone, Amphotericin B, Amascrine and sodium nitroprusside.

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 at 2° to 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.

6.6 Special precautions for disposal

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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8. MARKETING AUTHORISATION NUMBER(S)

PL 08828/0028

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10 DATE OF REVISION OF THE TEXT

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