

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucose 20% IV Infusion BP, as Steriflex No. 31 and **freeflex**

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Steriflex 31 has the following composition:

Name	Specification Reference	% w/v
Glucose Monohydrate for Parenteral Use	EP	22.0
<i>(Equivalent to Anhydrous Glucose)</i>		<i>20.0</i>

3 PHARMACEUTICAL FORM

Solution for infusion.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

The product is used 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. It may be combined with amino acid solutions in parenteral nutrition.

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 via a central vein.

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 20% IV Infusion BP, as Steriflex No. 31 and freeflex may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5 and 4.8).

4.3. Contra-Indications

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

Rebound hypoglycaemia may occur following the use of concentrated solutions of glucose.

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 has not been assessed but its use in this period is not considered to constitute a hazard.

Glucose 20% IV Infusion BP, as Steriflex No. 31 and freeflex 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		
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 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 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. Pre-clinical Safety Data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

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

6.2. Incompatibilities

Incompatible with blood, frusemide, hydralazine cyanocobalamin, kanamycin sulphate, novobiocin sodium or warfarin 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 at 2° to 25°C

6.5. Nature and Content of Container

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

- A hermetically sealed polythene bag.
- A rectangular pouch consisting of polyamide/polythene composite
- 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. Instructions for Use, Handling and 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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WA7 1NT

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0029

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/02/2009

10 DATE OF REVISION OF THE TEXT

19/03/2019