SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion BP 5%, as Steriflex No.6 or freeflex®

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Steriflex No. 6 has the following composition:

Name	Specification Reference	%w/v
Glucose Monohydrate for Parenteral Use BP	EP	5.5
(Equivalent to Anhydrous Glucose BP	EP	5.0

3 PHARMACEUTICAL FORM

Intravenous infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The produce is indicated 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.

The smaller volume containers may be used as a diluent and delivery system when administering compatible drug additives so as to avoid the risk of any over dilution of the additive drug.

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.

Use as a Diluent
When using this product as a diluent or vehicle for administration of drug additives, consult the prescribing information or data sheet of the drug to be used.

Method of administration

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. Glucose Infusion BP 5% as Steriflex No. 6 or freeflex or freeflex+ 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

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

The physician should also be altered to the possibility of adverse reactions to drug additives diluted and administered in this container. Prescribing information for additives to be administered in this manner should be consulted.

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

Glucose Infusion BP 5% as Steriflex No. 6 or freeflex or freeflex + 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).

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

Pharmacotherapeutic group: Blood substitutes and Perfusion solutions.
(ATC Code: B05BB02)

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Incompatible with blood, frusemide, hydralazine cyanocobalamin, kanamycin sulphate, novobiocin sodium or warfarin sodium.

6.3 Shelf life

50, 100, 150 & 250ml PVC Bags - 18 months.
500 & 1000ml PVC Bags – 24 months
50, 100 & 150ml Polyolefin Bags - 24 months.
250, 500 & 1000ml Polyolefin Bags – 36 months

6.4 Special precautions for storage

Store between 2°C and 25°C

6.5 Nature and contents of container

The container is a flexible 50, 100, 150, 250, 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 50, 100, 150, 250, 500 or 1000ml polyolefine bag sealed in a polyolefine overwrap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

<u>Opening the overwrap:</u>
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.

<u>Setting up the solution:</u>
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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court, Eastgate Way
Manor Park, Runcorn
Cheshire
WA7 1NT
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0095

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/04/2005

10 DATE OF REVISION OF THE TEXT

31/08/2021