SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the medicinal product

Trade name: Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP

International non-proprietary name *(INN):* Sodium chloride and Dextrose monohydrate

1.2 Strength: 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100mls contain sodium chloride 0.9gms and Dextrose monohydrate 5 Gms

There are no excipients.

Water for injection is used as a solvent.

3. PHARMACEUTICAL FORM

Solution for infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP is used as a source of fluid and carbohydrates and to dilute or deliver other medicines that can be given by infusion.

4.2 Posology and method of administration

Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP is administered by a doctor or a nurse. The doctor will decide on how much to administer and when it is to be given. This will depend on the patient's age, weight, condition, the reason for treatment and whether or not the infusion is being used to deliver or dilute another medicine. Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP will usually be administered through a plastic tube attached to a needle in a vein. Sodium Chloride 0.9% w/v & Glucose 5% w/v. Intravenous Infusion BP should be given slowly to prevent the patient producing too much urine (osmosis diuresis). The amount administered may also be affected by other treatments the patient is receiving. Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP should NOT be administered after the expiry date, which is stated on the container label. The expiry date refers to the last day of the month. Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP must not be administered if there are particles floating in the solution or if the pack is damaged in any way. Any unused solution should be thrown away. Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP must NOT be administered from a bottle that has been partly used.

4.3 Contraindications

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

4.4 Special warnings and precaution for use

Do not use if the container is found leaking upon squeezing, if the solution is not clear or if the solution contains particulate matter.

Please verify if the patient has had any of the following medical conditions:

• Congestive Heart failure

• Respiratory failure (lung disease)

• Renal Disease

• Primary Hyperaldosteronism

• Reduced production of urine (oliguria or anuria)

• Excess water in the body (water intoxication)

• Head injury within 24 hours

• A high pressure within the skull (intracranial hypertension)

• A stroke due to a clot in a blood vessel in the brain (ischaemic stroke)

• Allergy to corn (Sodium Chloride 0.9%w/v & Glucose 5% w/v Intravenous Infusion BP contains glucose derived from corn) When this infusion is administered, the patient's blood and urine samples must be taken to monitor:

• Electrolyte concentrations in their blood (plasma electrolytes)

• The amount of glucose

As Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP contains glucose, it can cause a high level of glucose in the blood (hyperglycaemia) and high level of sodium in the blood (hypernatraemia). If this occurs, you may:

• Adjust the speed of infusion

• Give insulin to reduce the patient's blood glucose levels

• Monitor electrolytes in blood

This is particularly important:

• If the patient diabetic

• If the patient's kidneys do not work as well as normal

• If the patient has recently had a stroke (acute ischaemic stroke). High levels of glucose in the blood can worsen the effects of stroke and affect recovery.
• If the patient suffers from Hyperchloraemia • In disorders where restriction of Sodium intake is required, such as cardiac insufficiency, generalized oedema, hypertension, eclampsia, and severe renal insufficiency Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together.

4.5 Interactions with other medicinal products and other forms of interaction

Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP and other medicines taken at the same time can affect each other. As with all parenteral solutions, before adding medication, assess the compatibility of the additives with Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP. It is the responsibility of the prescriber to judge the incompatibility of the additive with Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP by checking eventual colour change, or formation of precipitate, insoluble complexes or crystals.
Do not administer Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP with certain hormones (catecholamines) including adrenaline or steroids as they can increase the level of glucose in the blood.
Caution must be exercised in the administration of Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP to patients receiving corticosteroids or corticotrophins as these are associated with the retention of sodium and water.

4.6 Pregnancy and lactation

There is no adequate data from the use of Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP.
Caution is advised in patients with pre-eclampsia.
If another medicine is to be added to the solution for infusion during pregnancy or breast-feeding, read the patient information leaflet of the medicine that is to be added.

Use in Children

Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP should be given with special care in children. There is no specific paediatric dose; the dose is dependent on weight, clinical condition and laboratory results.

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes.

New-borns, especially those born premature and with low birth weight- are at increased risk of developing too low or too high level of glucose in the blood (hypo or hyperglycaemia) and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate control of the glucose levels in order to avoid potential long term adverse effects. Low glucose levels in the new-born can cause prolonged seizures, coma and brain damage. High glucose levels have been associated with bleeding into the brain, bacterial and fungal infections, damage to the eye (retinopathy or prematurity), infections in the intestinal track (necrotizing enterocolitis), lung problems (bronchopulmonary dysplasia), prolonged length of hospital stay and death.

When administered to a newborn baby, the solution bottle shall be connected to an infusion pump device, which allows exact delivery of the required quantity of solution across the defined time interval. The device must be monitored by the doctor or nurse to ensure safe administration.

4.7 Effects on ability to drive and use machines

This product does not affect ability to drive and use machines.

4.8 Undesirable effects

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects can include:

• Changes in the amounts of chemicals in the blood (electrolyte disturbances)

• Higher than normal amount of glucose in the blood (hyperglycaemia)

• Loss of water in the body (dehydration)

• Excessive urination (polyuria)

• Hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn)

• Fever (pyrexia)
• Chills
• Metabolic acidosis
• Tremor
• Rash, pruritus
• Hypernatraemia leading to osmotically induced water shift, decreasing intracellular volume i.e. dehydration or internal organs especially the brain causing thrombosis and hemorrhage
• Reactions due to administration technique: Fever (febrile response)
• Infection at the site of infusion
• Local pain or reaction (redness or swelling at the site of infusion)
• Irritation and inflammation of the vein into which the solution is infused (phlebitis).
This can cause redness, pain or burning and burning along the path of the vein into which the solution is infused.
• The formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling and pain in the area of the clot.
• Escape of the infusion solution into the tissue around the vein (extravasation).
This can damage the tissue and cause scarring. If a medicine has been added to the solution for infusion, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. Please read the patient information leaflet of the added medicine for a list of possible symptoms. If any side effect occurs, the infusion must be stopped.

4.9 Overdose.

If Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP v is administered in a larger quantity (over-infusion) or administered too fast, this may lead
to the following symptoms:
• Build up of the liquid in the tissues causing swelling (oedema) or water intoxication with lower than normal amount of sodium in the blood (hyponatraemia)
• An increase in the amount of urine the patient produces (osmotic diuresis)
• The blood becomes too concentrated (hyperosmorality)
• A loss of water in the body (dehydration)
• A high blood glucose level (hyperglycaemia)
• Glucose in urine (hyperglycosuria)

• Hypernatraemia
• Hyperchloraemia
• Hyperhydration
• Hyperosmolarity of the serum
• Metabolic acidosis

If any of the above symptoms are developed by the patient, stop the infusion immediately and treat the symptoms.

If a medicine has been added to the Sodium Chloride 0.9% w/v & Glucose 5% w/v Intravenous Infusion BP before over-infusion occurs, that medicine may also cause symptoms. Ensure you read the patient information leaflet of the added medicine for a list of possible symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

When administered intravenously, these solutions provide a source of water, carbohydrate and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of dextrose and of sodium chloride is suitable for parenteral maintenance or replacement of water and electrolyte requirements with minimal carbohydrate calories.

Solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total

body weight. Average normal adult daily requirements range from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production). Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na+) plays a major role in maintaining physiologic equilibrium.

- **Pharmacotherapeutic group:** Electrolytes with carbohydrates for Intravenous infusion
- **ATC CODE:** B05BB02.

5.2 Pharmacokinetic properties

Dextrose is rapidly absorbed from the gastrointestinal tract. Peak plasma concentrations of dextrose
occur about 40 minutes after oral doses in hypoglycemic patients. It is metabolized via pyruvic or
lactic acid to carbon dioxide and water with the release of energy. All body cells are capable of oxidizing dextrose and it forms the principal source of energy in cellular metabolism.
Sodium chloride is well absorbed from the gastrointestinal tract. Excess sodium is mainly excreted
by the kidney, and small amounts are lost in the faeces and sweat

5.3 Preclinical safety data

There is no documented pre-clinical safety data of relevance to the prescriber**.**
It is not applicable because glucose has been used in clinical practice for many years and its effect in man are well known.

6. PHARMACEUTICAL PARTICULARS

6.1 list of excipients

There are no excipients.

6.2 Incompatibilities

Compatibilities should be checked when additives are used, as additives may Be incompatible. As with all parenteral solutions, before adding medications, Compatibility of the additives with the container must be assessed. It is the responsibility of the user to judge the incompatibility of the additive with Dextrose in Sodium Chloride by checking eventual colour change, precipitate, insoluble complexes or Crystals. Before introducing any additive verify its solubility in water at pH of Dextrose in Sodium Chloride Infusion solution. When compatible additive is added to this

formulation, the solution must be administered immediately, unless dilution has Taken place in controlled and validated aseptic conditions. Addition of sodium chloride to Mannitol solution (20/25%) may precipitate Mannitol.

6.3 shelf-life

36 months

6.4 Special precautions for storage

Keep this medicine out of sight and reach of children.

Store below 30°C.

6.5 Nature and contents of container

What material is the container of the fluid made of?

The bottle is a Closed System Container (CSC) which is a plastic collapsible container fabricated from low density polyethylene (LDPE). The container is capable of standing upright. The container is produced in an automatic one-step blow fill seal process with a hanger completely embedded in the base of the container. The LDPE used in fabrication of the bottle is resistant to high temperature which enables sterilisation of the products via hot water shower sterilizer.
The container is formed with euro head where a twin-port cap is welded. The Twin Cap has injected thermoplastic elastomers (TPE) closure. This system provides two injection ports and resealing ports for the infusion giving set thus giving a high level of drug delivery and administration practice

Is the fluid container collapsible?

Yes, the fluid container is self-collapsible. A closed drug delivery system is achieved as the container design allows for easy fluid flow dynamics thus avoiding the risky unconventional local/regional practice of providing a flow vent in a non-collapsible container with a needle pierced through the container wall in a risky hospital environment prone to infectious disease carriers.

What container closure system is provided?

The bottle is a closed system container. This system provides two injection ports and resealing ports for the infusion giving set thus giving a high level of drug delivery and administration practice.

6.6 Special precautions for disposal

Discard the unused contents and bottles in which contents have been used.

Don’t use if crystals have separated.

Don’t drain the contents in the sinks or water system.

7. REGISTRANT

B. BRAUN PHARMACEUTICALS EPZ LTD.

L.R. No. 18474/84, Athi River

P.O. Box 51200-00100

Nairobi, Kenya

8. 1 MANUFACTURER

B. BRAUN PHARMACEUTICALS EPZ LTD.

L.R. No. 18474/84, Athi River

P.O. Box 51200-00100

Nairobi, Kenya

8.2 MARKETING AUTHORIZATION HOLDER.

B. BRAUN PHARMACEUTICALS EPZ LTD.

L.R. No. 18474/84, Athi River

P.O. Box 51200-00100

Nairobi, Kenya

9. Date of revision of the text

December 2023

10. Dosimetry

Not applicable

11. Instructions for preparation of radiopharmaceuticals.

Not applicable

Product registration No. in Kenya:

H2013/CTD1343/270