SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 name of the medicinal product

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

International non-proprietary name *(INN):* Sodium Chloride

1.2 Strength

Each 100ml contains Sodium Chloride 0.9gms

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Batch size: 1500 Ltrs.

Ingredients	**Administration Unit 500**ML		**Bioequivalent Batch number** N/A		**Primary stability Batch number 04E02**		**Production Batch number 04E02**	
	Mg/ unit	%*	Kg	%*	Kg	%*	kg	%*
Active :								
Sodium chloride	4500mg	0.9	N/A	N/A	13.5kg	0.9	13.5kg	0.9
Excipients:								
Water for injectionQs	500mls	QS	N/A	N/A	QS	QS	QS	QS

3. PHARMACEUTICAL FORM

Solution infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Sodium Chloride Intravenous Infusion BP 0.9% w/v 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, and condition, the reason for treatment, blood levels and whether or not the infusion is being used to deliver or dilute another medicine.

Sodium Chloride Intravenous Infusion BP 0.9% w/v will usually be administered through a plastic tube attached to a needle in a vein. In the average adult, daily requirements of sodium and chloride are met by infusion of one litre of 0.9% w/v Sodium Chloride (150 mEq each of Sodium and Chloride) with an infusion rate of up to 40ml/kg body weight/hour. In the management of shock higher volumes and higher rates of infusion may be administered. In patients with chronic hypernatremia the rate of infusion should be slow so that the resulting increase of the serum sodium level is limited to a maximum of 0.35mmol/l/h. The amount administered may also be affected by other treatments the patient is receiving. Sodium Chloride Intravenous Infusion BP 0.9% w/v 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 Intravenous Infusion BP 0.9% w/v 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 Intravenous Infusion BP 0.9% w/v must NOT be administered from a bottle that has been partly used. 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.

4.3 Contraindications.

DO NOT administer Sodium Chloride Intravenous Infusion BP 0.9%w/v if the patient is suffering from any of the following conditions:

- Severe Renal impairment
- Risk of fluid / solute overload and electrolyte disturbances
- Hypernatremia
- Hyperchloraemia
- Metabolic acidosis
- Hypervolemia

If another medicine is to be added to the solution for infusion always read the patient information leaflet of that medicine. This way you can check to see if that medicine is safe to be administered with the infusion to the patient.

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
- Renal Disease
- Hypertension
- Primary Hyperaldosteronism

When this infusion is administered, the patient's blood samples must be taken to monitor:

- Electrolyte concentrations in their blood (plasma electrolytes)

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

- Adjust the speed of infusion
- Monitor electrolytes in blood

This is particularly important:
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.

4.5 Interactions with other medicinal products and other forms of interaction
Sodium Chloride Intravenous Infusion BP 0.9% w/v and other medicines taken at the same time can affect each other. Caution must be exercised in the administration of Sodium Chloride Intravenous Infusion BP 0.9% w/v to patients receiving corticosteroids or corticotrophins as these are associated with the retention of sodium and water.

4.6 Pregnancy and lactation
There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride Intravenous Infusion BP 0.9% w/v.
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
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.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects can include:
- Metabolic acidosis
- Tremor
- Rash, pruritus
- Hypernatremia leading to osmotically induced water shift, decreasing intracellular volume i.e. dehydration or internal organs especially the brain causing thrombosis and haemorrhage
- 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.

4.9 Overdose.

If Sodium Chloride Intravenous Infusion BP 0.9% w/v is administered in a larger quantity (over-infusion) or administered too fast, this may lead to the following symptoms:

- Hypernatremia)
- Hyperchloraemia
- Hyper hydration
- 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.

Administer diuretics with continuous monitoring of serum electrolytes and correction of acid-base imbalances.

If a medicine has been added to the Sodium Chloride Intravenous Infusion BP 0.9% w/v 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

- **Pharmacotherapeutic group**: Electrolyte for intravenous Infusion
- **ATC CODE:** B05BB01

  Sodium Chloride 0.9% w/v I.V infusion has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient. Sodium is the major cation of the extracellular fluid and functions primarily in the control of water distribution, fluid balance and osmotic pressure of body fluids. Sodium is also used with Chloride and Bicarbonate in the regulation of the acid-base equilibrium of body fluid. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the Chloride concentration. An increase in the Sodium content of the body also means reduction of the body's free water content independent of the serum osmolality. A 0.9% w/v Sodium Chloride solution has the same osmolality as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only a 1/3 of the administered volume remains in the intravascular space. Therefore the haemodynamic effect of the solution is of short duration.

5.2 Pharmacokinetic properties

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Bioavailability:

Parenteral solution goes directly into the Systemic Circulation, so, its bioavailability is 100% at the site of action.

KINETICS SUMMARY

Onset: - immediate

Peak: - immediate

Duration: - until renal clearance occurs

5.3 preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 list of excipients

There are no excipients.

6.2 incompatibilities

Not applicable.

6.3 shelf-life

24 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 container is made from pharmaceutical grade Low Density Poly-Ethylene complying with Pharmacopoeia requirements of plastics for packaging of preparations for parenteral use. The inert material offers drug compatibility. As the container material does not contain any additives there is no leaching of any substance into the drug solution.

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 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

No special precautions are required.

7. REGISTRANT

B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84, Athi River
P.O. Box 51200-00100Nairobi, Kenya

8. 1 MANUFACTURER

B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84, Athi River
P.O. Box 51200-00100Nairobi, Kenya

8.2 MARKETING AUTHORIZATION HOLDER.

B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84, Athi River
P.O. Box 51200-00100Nairobi, Kenya

9. Date of revision of the text

April 2019

10. Dosimetry – Not applicable

11. Instructions for preparation of radiopharmaceuticals. Not applicable

Product registration No. in Kenya: H2007/141/18128