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SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

1.1 Product Name

0.9% SODIUM CHLORIDE EZ/FLUSH

1.2 Strength

Each mL contains:

Sodium Chloride	9 mg

1.3 Pharmaceutical Dosage Form

Solution for injection

2. Qualitative and quantitative composition

2.1 Qualitative Declaration

Sodium Chloride

2.2 Quantitative Declaration

Each mL contains:

Sodium Chloride	9 mg

3. Pharmaceutical form

Sterile solution

4. Clinical particulars

4.1 Therapeutic indication

1. For use in prophylactic and replacement therapy, requiring the use of isotonic saline solution.
2. In the reconstitution, dilution and making up of certain drugs.
3. For dilution of solutions for nebulization.
4. As a saline irrigant for tracheal lavage and flushing IV catheters.

4.2 Posology and method of administration

As directed by physician.

In the prophylaxis or replacement therapy of extracellular fluid deficits, the dosage of 0.9% SODIUM CHLORIDE EZ/FLUSH is dependent on the age, weight, clinical status and degree of deficiency, and must be determined on the individual basis.

4.3 Contraindications

There are no absolute contraindications to use of 0.9% SODIUM CHLORIDE EZ/FLUSH

4.4 Special warning and precautions for use

0.9% SODIUM CHLORIDE EZ/FLUSH should be administered with caution to patients with congestive cardiac failure, pre-eclampsia, impaired renal function or oedema with sodium retention. Care is also required with administering this solution to very young or to elderly patients. Pseudohyponatremia is a condition in which spuriously low concentrations of sodium are found when plasma sodium is measured by conventional methods. It may occur when there is an abnormally high concentration of large molecules and hence an abnormally low percentage of plasma water. This may occur in hyperlipidemia and hyperproteinemia and has also been reported in patients with diabetes mellitus. Correct values may be obtained by referring the concentration to plasma water.

Before use, ensure that the container is undamaged and the contents clear in appearance. After use, discard any remaining solution.

4.5 Interactions with other medicinal products and other forms of interactions

Concomitant administration of other sodium salts, may contribute to the sodium load. Only use as a pharmaceutical diluent where indicated in the manufacturer's literature.

4.6 Pregnancy and lactation

0.9% SODIUM CHLORIDE EZ/FLUSH is physiological saline and may be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Injudicious intravenous saline therapy (e.g. post-operative and in patients with impaired cardiac or renal function) may cause hypernatraemia. Osmotically induced water shift decreases intracellular volume, resulting in dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage. General adverse effects of sodium chloride excess in the body include: nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivary and lachrymal secretions, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate, with an acidifying effect. With judicious use of intravenous saline therapy these side effects can be avoided. If administered sub-cutaneously, any addition to the isotonic solution could render it hypertonic and cause pain at the site of injection.

4.9 Overdose

Injudicious intravenous saline therapy (e.g. post-operatively or in patients with impaired cardiac or renal function) may cause hypernatraemia. Osmotically induced water shift decreases intracellular volume, resulting in

dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage. General adverse effects of sodium chloride excess in the body include: nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivary and lachrymal secretions, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate, with an acidifying effect. With judicious use of intravenous saline therapy these side effects can be avoided.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The principal determinant of the effective osmolality of the extracellular fluids (and also of the intracellular fluids, since they remain in osmotic equilibrium with the extracellular fluids) is the extracellular fluid sodium concentration. The reason for this is that sodium is the most abundant positive ion of the extracellular fluid. Negative ion concentrations of the body fluids are adjusted to equal those of the positive ions by renal acid-base control mechanisms. Furthermore, glucose and urea, the most abundant of the non-ionic osmolar solutes in extracellular fluids, normally only represent about 3% of the total osmolality. Therefore, in effect, the extracellular fluid sodium ion concentration controls over 90% of the effective osmotic pressure of the extracellular fluid. Sodium Chloride remains the most important single salt for prophylaxis or replacement therapy of deficits of extracellular fluid. Volume contraction, whether isotonic, hypotonic or hypertonic, may seriously impair the circulation (cardiac output falls and microcirculation is compromised) and prompt infusion of isotonic sodium chloride solution is indicated.

5.2 Pharmacokinetic properties

The homeostatic mechanisms involved in maintaining constant ion concentrations are well described in standard text books of physiology and biochemistry and are not, therefore, included here.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Prefilled Syringe (PFS) of 3, 5, 10 and 20 mL, individually packed or unpacked in plastic sachet.

Packed or unpacked in a paper box of 10, 20, 50, 100 and 200 sachets.

7. Marketing authorisation holder

PHARMA INNOVA COMPANY LIMITED

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Lam Luk Ka, Pathumthani 12150, Thailand

Tel. (662) 532-7181 Fax (662) 532-7019

8. Marketing authorisation number(s)

xx xxx/xx

9. Date of first authorization/ renewal of the authorization

DD/MM/YYYY

10. date of revision of the text

10 March 2021