AUSTRALIAN PRODUCT INFORMATION – SODIUM CHLORIDE INJECTION BP 0.9%

1 NAME OF THE MEDICINE

Sodium Chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride Injection BP 0.9%is a sterile, preservative-free solution, containing sodium chloride 0.9% w/w in Water for Injections.

3 PHARMACEUTICAL FORM

Injection, solution

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Sodium Chloride Injection BP 0.9% can be used as the vehicle for many parenteral drugs and as an electrolyte replenisher for maintenance or replacement of deficits of extracellular fluid. It can also be used as a sterile irrigation medium.

4.2 DOSE AND METHOD OF ADMINISTRATION

To be used as directed by a physician.

Parenteral drug products should be inspected prior to administration for particulate matter and discolouration. Sodium Chloride Injection BP 0.9% does not contain any antimicrobial preservatives. Care should be taken with intravenous technique to avoid injection site reactions and infections.

Dosage is dependent on the age, weight, clinical and fluid/electrolyte condition of the patient.

4.3 CONTRAINDICATIONS

- Congestive heart failure
- Severe renal impairment
- Conditions of sodium retention and oedema
- Liver cirrhosis

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- Solutions containing sodium chloride should be used cautiously in patients with cardiovascular or renal disease, pregnancy associated hypertension, pulmonary

or peripheral oedema, those receiving corticosteroids or corticotrophin or any condition associated with sodium retention.

- Excessive administration of sodium chloride solution may result in hypernatraemia, resulting in dehydration of internal organs, hypokalaemia and acidosis. Monitoring of fluid, electrolyte and acid-base balance may be necessary
- When used as a vehicle for intravenous drug delivery, the Product Information document of such drugs should be checked prior to use to ensure compatibility with the sodium chloride solution. Reconstitution instructions should be read carefully.
- Do not use unless the solution is clear.

Use in the elderly

Sodium chloride solutions should be used with caution in geriatric patients.

Paediatric use

Sodium chloride solutions should be used with caution in infants.

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

- Additives may be incompatible with sodium chloride.
- Do not store solutions containing additives unless compatibility has been proven.
- Do not administer such preparations unless the solution is clear.
- Co-medication of drugs inducing sodium retention may exacerbate any systemic effects.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Safety in pregnancy has not been established. Use is recommended only when clearly indicated

Use in lactation.

Safety in lactation has not yet been established. Use of this product whilst breastfeeding is recommended only when potential benefits outweigh potential risks to the newborn.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

- Proper use of normal saline as a vehicle for parenteral drugs or as an electrolyte replacement therapy is unlikely to result in adverse effects.
- If any adverse reactions are observed during administration, discontinue treatment and institute appropriate supportive treatment.
- Thrombophlebitis may occur at the injection site during prolonged infusions.
- Excess intravenous administration of sodium chloride may cause hypernatraemia, hypokalaemia and acidosis.
- Hypernatraemia rarely occurs with therapeutic doses of sodium chloride, but may occur in excessive administration. A serious complication of this is dehydration of the brain causing somnolence and confusion, which may progress to convulsions, coma and ultimately respiratory failure and death. Other symptoms include thirst, reduced salivation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, weakness and irritability.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms of overdosage:

Excess sodium chloride within the body may produce the following general gastrointestinal effects: nausea, vomiting, diarrhoea and cramps.

Salivation and lacrimation are reduced, whilst thirst and swelling are increased.

Possible other symptoms include hypotension, tachycardia, renal failure, peripheral and pulmonary oedema and respiratory arrest.

Symptoms of the CNS include headache, dizziness, irritability, restlessness, weakness, muscle twitching or rigidity, convulsions, coma and death.

Treatment of overdosage:

Normal plasma sodium concentrations should be restored at no more than 10-15 mmol/day with IV hypotonic saline. Dialysis may be required if there is renal impairment, if plasma sodium levels are greater than 200 mmol/L or if the patient is moribund. Convulsions should be treated with diazepam.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Sodium Chloride Injection BP 0.9% provides a source of sodium ions (154 mmol/L), chloride ions (154 mmol/L) and water. With an osmolarity of approx. 308 mosmol/L, the product is isotonic, and therefore designated as physiological sodium chloride solution.

Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of the sodium cation in maintenance of acid-base balance, isotonicity and electrodynamic characteristics of cells.

Clinical trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

As sodium chloride intravenous preparations are directly administered to the circulation, the bioavailability of the components is 100%. Excess sodium is predominantly excreted by the kidneys, with small amounts lost in faeces and sweat.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available

Carcinogenicity

The active ingredients sodium and chloride are not carcinogenic or mutagenic. They are basic cellular components.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for Injections

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Sodium Chloride Injection BP 0.9% 5 mL polypropylene ampoule (pack of 50)

Sodium Chloride Injection BP 0.9% 10 mL polypropylene ampoule (pack of 50)

Sodium Chloride Injection BP 0.9% 20 mL polypropylene ampoule (pack of 20)

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

For use in one patient on one occasion only. Discard any remaining portion

6.7 PHYSICOCHEMICAL PROPERTIES

Sodium chloride is a white, crystalline powder or colourless crystals, freely soluble in water and practically insoluble in ethanol.

pH 4.5-7.0

Chemical structure

Molecular formula: NaCl

Molecular weight: 58.44

CAS number

7647-14-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

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9 DATE OF FIRST APPROVAL

22 December 2015

10 DATE OF REVISION

29 Sep 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
8	Update to sponsor details due to Sponsor transfer from Mayne Pharma International Pty Ltd to InterPharma Pty Ltd – minor editorial change
ALL	PI reformat - minor editorial changes made