PRODUCT INFORMATION

SODIUM CHLORIDE IRRIGATION SOLUTION 0.9%

(sodium chloride)

NAME OF THE MEDICINE

Sodium chloride BP

The molecular formula is NaCl and the molecular weight is 58.44

CAS Number: 7647-14-5

DESCRIPTION

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

Sodium Chloride Irrigation Solution 0.9% is a clear, colourless, sterile, isotonic, preservative-free solution for irrigation containing Sodium Chloride BP 0.9% in Water for Injections BP.

PHARMACOLOGY

Pharmacodynamics

Sodium Chloride Irrigation Solution exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes. It also acts as diluent or vehicle for other pharmaceutical preparations.

Sodium is the major cation of the 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 the maintenance of acid-base balance, isotonicity and electrodynamic characteristics of cells.

INDICATIONS

- during surgical procedures where an isotonic irrigation is required e.g. irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes.
- dilution of medications prior to use in accordance with the product information for the medication being diluted e.g. to dilute inhalation solutions prior to nebulisation

CONTRAINDICATIONS

Sodium Chloride Irrigation Solution should not be used for irrigation during electrosurgical procedures.

Sodium Chloride Irrigation Solution should not be used for intravenous injection or injection by other usual parenteral routes.

Do not use unless the solution is clear and the seal is intact.

PRECAUTIONS

For external use only. Not for injection, for irrigation only.

Sodium Chloride Irrigation Solution should generally not be used in conditions in which systemic absorption is likely to result. It is possible that an amount may enter the systemic circulation depending on the nature of the surgical procedure.

Systemic absorption of irrigation solutions may cause fluid and/or solute overload resulting in dilution of serum electrolytes, overhydration, congestive conditions or pulmonary oedema.

The risk of dilutional conditions is inversely proportional to the electrolyte concentration administered and the risk of solute overload and resultant congestive conditions with peripheral and/or pulmonary oedema is directly proportional to the electrolyte concentration administered.

Given the possibility of systemic absorption of irrigation solutions, Sodium Chloride Irrigation Solution 0.9% should be used with caution in patients with congestive heart failure, renal impairment, liver cirrhosis, or any condition characterised by sodium retention and oedema.

If adverse effects, overhydration or solute overload occurs with Sodium Chloride Irrigation Solution, it should be discontinued, the patient closely evaluated and appropriate corrective therapy instituted, if necessary.

The contents of an opened container should be used promptly to minimise a possibility of bacterial growth or pyrogen formation. Discard the unused portion of irrigating solution, since no antibacterial agent has been added.

Use in Pregnancy: Category A

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

Use in Lactation

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

Depending on the surgical procedure during which this product is used for irrigation, various amounts of sodium chloride may enter the systemic circulation. It is likely that the proportion of the systemically absorbed sodium and chloride ions would be subsequently excreted into milk.

Genotoxicity

The active ingredients sodium and chloride are not mutagenic**.**

Carcinogenicity

The active ingredients sodium and chloride are not carcinogenic.

INTERACTIONS WITH OTHER MEDICINES

- Additives may be incompatible with Sodium Chloride Irrigation Solution 0.9%.
- Product Information documents of intended medications for mixing should be checked beforehand to avoid incompatibility.
- Do not store Sodium Chloride Irrigation Solution after mixing with any additives.
- Co-medication of drugs inducing sodium retention may exacerbate any systemic effects caused by this irrigation solution.

ADVERSE EFFECTS

- Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities.
- Excessive volume or pressure during irrigation of closed cavities may result in distension or disruption of tissues.
- Inadvertent contamination from careless technique may transmit infection.

- Adverse effects resulting from irrigation of body cavities, tissues or indwelling catheters and tubes are usually avoidable when appropriate procedures are followed.
- If a large quantity of Sodium Chloride for Irrigation Solution is absorbed during a surgical procedure, fluid overload and electrolyte disturbance may result. See **PRECAUTIONS** and **OVERDOSAGE**.
- If an adverse reaction does occur, discontinue the administration of the irrigating solution, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

Sodium Chloride Irrigation Solution must not be administered by parenteral injection. The use of aseptic technique is essential when the irrigation solution is used for irrigation of body cavities, wounds and urethral catheters.

Dosage of Sodium Chloride Irrigation Solution depends on the capacity or surface area of the structure to be irrigated and the nature of the procedure. When it is used as a diluent or vehicle for other drugs, the manufacturer's recommendations should be followed. Specialised references should be consulted for specific information on the compatibility of additives.

OVERDOSAGE

If poisoning occurs, contact a doctor or Poisons Information Centre.

Symptoms

While systemic overdose would be extremely rare when used as directed, excess sodium chloride in the body may produce gastrointestinal side-effects such as nausea, vomiting, diarrhoea and cramps. Salivation and lacrimation are reduced, whilst thirst is increased. Other possible symptoms include hypotension, tachycardia, headache, dizziness, weakness, muscle twitching or rigidity, peripheral and pulmonary oedema and respiratory arrest.

Treatment

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

PRESENTATION AND STORAGE CONDITIONS

Presentation

Sodium Chloride Irrigation Solution 0.9% (sterile) is presented in 30 mL Steritube®, pack of 30's. AUST R 11290

Storage

Store below 25 °C.

Single use only. Discard unused portion.

The expiry date (month/year) is stated on the package after EXP.

NAME AND ADDRESS OF THE SPONSOR

Sponsor

Pfizer Australia Pty Ltd
A.B.N. 5000 8422 348
38-42 Wharf Road
WEST RYDE NSW 2114

Manufacturer

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
15 Brodie Hall Drive,
Bentley WA 6102 Australia

POISON SCHEDULE OF THE MEDICINE

Unscheduled

DATE OF FIRST INCLUSION IN THE ARTG

21 August 2001.

DATE OF MOST RECENT AMENDMENT

4 November 2016