PRESCRIBING INFORMATION

20% Sodium Chloride Injection, BP

20% w / v

For Intravenous Infusion after Dilution

Intravenous Fluid and Electrolyte Replenisher

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20% Sodium Chloride Injection, BP

WARNING: MUST BE DILUTED PRIOR TO ADMINISTRATION

Not for multiple-dose use. Do not inject without dilution. Use only if solution is clear. No preservative added; the contents of the clearflex plastic bag should be promptly used.

CONCENTRATED SOLUTIONS SUITABLE FOR USE ONLY AFTER DILUTION WITH COMPATIBLE I.V. FLUIDS TO CORRECT HYPONATREMIA WHEN ORAL REPLACEMENT IS NOT FEASIBLE.

DESCRIPTION

20% Sodium Chloride Injection, BP is a sterile, nonpyrogenic, concentrated solution for intravenous administration **ONLY AFTER DILUTION** to replenish electrolytes. The preparation contains 3.422 mEq/mL (20%) sodium chloride, in water for injection, EP. The solution contains no bacteriostat, antimicrobial agent or added buffer; the pH of the solution ranges from 5 to 7.5. Each mL contains: sodium chloride 200 mg; water for injection q.s. May contain hydrochloric acid to adjust the pH. The osmolar concentration of the 3.422 mEq/mL solution is 6.844 mOsmol/mL (calculated). Sodium chloride is chemically designated NaCl and is a white crystalline compound freely soluble in water.

A pharmacy bulk package is a sterile dosage form containing many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for I.V. infusion.

CLINICAL PHARMACOLOGY

Sodium chloride dissociates in water to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of body fluids (mainly extracellular) and are essential for maintaining electrolyte balance.

Sodium is the principal cation of extracellular fluid. It stands for more than 90% of total cations at its normal plasma concentration (approximately 142 mEq/L). While the sodium ion can diffuse across cell membranes, intracellular sodium is maintained at a much lower concentration than extracellular sodium through the expenditure of energy by the cell (sodium-potassium pump). Loss of intracellular potassium ions is usually accompanied by an increase in intracellular sodium ion.

When serum sodium concentration is low, the secretion of antidiuretic hormone (ADH) by the pituitary is inhibited, thereby preventing water reabsorption by the distal renal tubules. On the other hand, adrenal secretion of aldosterone increases renal tubular reabsorption of sodium in an effort to re-establish normal serum sodium concentration.

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.

INDICATIONS AND USAGE

20% Sodium Chloride Injection, BP is indicated for parenteral restoration of sodium ion in patients with restricted oral intake. Sodium replacement is specifically indicated in patients with hyponatremia or low salt syndrome. 20% Sodium Chloride Injection, BP may also be added to compatible carbohydrate solutions such as dextrose in water to provide electrolytes. After available clinical and laboratory information is considered and correlated, the appropriate number of millimoles of 20% Sodium Chloride Injection, BP is taken and diluted for use.

CONTRAINDICATIONS

20% Sodium Chloride Injection, BP is contraindicated in patients with hypernatremia or fluid retention.

WARNINGS

See boxed "WARNING" at top of the Prescribing Information or package insert.

Inadvertent direct injection or absorption of concentrated sodium chloride solution may give rise to sudden hypernatremia and such complications as cardiovascular shock, central nervous system disorders, extensive haemolysis, cortical necrosis of the kidneys and severe local tissue necrosis (if administered extravascularly).

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

In patients with diminished renal function, administration of solutions containing sodium may result in sodium retention.

The intravenous administration of this solution (after appropriate dilution) can cause fluid and/or solute overloading resulting in dilution of other serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

Excessive administration of potassium free solutions may result in significant hypokalemia.

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of

calcium and phosphate solutions which contain aluminum. Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg per kg per day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of TPN products and of the lock-flush solutions used in their administration.

PRECAUTIONS

Storage of hypertonic solutions of sodium chloride should be restricted to a pharmacy. All required dilutions should be performed prior to dispensing.

Do not use unless the solution is clear and the clearflex plastic bag is intact. Discard any unused portion.

20% Sodium Chloride Injection, BP must be diluted before infusion to avoid a sudden increase in the level of plasma sodium. Too-rapid administration should be avoided.

Special caution should be used in administering sodium-containing solutions to patients with severe renal impairment, cirrhosis of the liver, cardiac failure, or other edematous or sodium-retaining states.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects:

Animal reproduction studies have not been conducted with sodium chloride. It is also not known whether sodium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Inadvertent administration of concentrated sodium chloride solution may result in tissue necrosis causing deformity and nerve damage as well as severe pain upon injection.

The direct injection or absorption of concentrated sodium chloride solution may also give rise to sudden hypernatremia and such complications as cardiovascular shock, central nervous system disorders, extensive haemolysis, cortical necrosis of the kidneys and severe local tissue necrosis (if used extravascularly).

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. (see **WARNINGS** and **PRECAUTIONS**.)

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

20% Sodium Chloride Injection, BP is administered intravenously **only after addition to a larger volume of fluid.** See boxes "WARNING" at top of insert. The dose, dilution and rate of injection are dependent upon the individual needs of each patient.

All or part of the contents of one or more additive containers may be added to an intravenous solution container. Concentrations of up to 5% sodium chloride have been administered.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solutions and container permit. See **PRECAUTIONS**.

HOW IT'S SUPPLIED

20% Sodium Chloride Injection, BP is available in a Clearflex plastic container as follows:

CLEARFLEX PLASTIC BAG

% NaCl	Na^+ mEq/mL
20%	3.422

STORAGE AND STABILITY

Store between 15-25°C. Do not freeze.

MORE INFORMATION

If you want more information about 20% Sodium Chloride Injection, BP:

- Talk to your healthcare professional
- Find the full Prescribing Information that is prepared for healthcare professionals by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.baxter.ca) or by calling 1-888-719-9955.

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