5/12610194/0911

Directions for Use

B. Braun Melsungen AG, 34209 Melsungen, Germany

0.9% w/v Sodium Chloride Intravenous Infusion BP

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in December 2010

Composition

Each 1000 ml contains	
Sodium Chloride	9.0 g
Water for Injections to	1000 ml
Osmolarity	308 mOsm/l
Electrolytes	mmol/l
Sodium	154
Chloride	154

Indications

Short - term intravascular volume substitution. Hypotonic dehydration or isotonic dehydration. Vehicle solution for supplementary medication Fluid and electrolyte replacement, hypochloremic alkalosis and chloride losses, externally for wound irrigation and moistening of wound tamponades dressings.

Dosage

The dosage guideline for adults:
Average dose: 1000 ml per day.
Flow rate:
Up to 180 drops/min, corresponding to 550 ml/h.
Maximum recommended dosage:
40 ml per KG body weight and per day, not more than 2000 ml per day.
Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determination.

Route of administration

I.V.; External.

Contraindications

Hyperhydration (e.g. water intoxication, oedema).
Hypernatraemia.
Caution is to be exercised in patients with hypokalaemia, hypernatraemia, and diseases requiring limitation of sodium intake, such as heart insufficiency, general oedema, pulmonary oedema, hypertension, eclampsia, severe kidney Insufficiency, cirrhotic disease, circulatory insufficiency, hypoproteinaemia.

Warnings

Fluid/solute overload; Excessive amounts of sodium chloride by any route may cause hypokalaemia and acidosis. Administration of IV solution can cause fluid or solute overload resulting in dilution of serum electrolyte concentrations, congestive heart failure (CHF), overhydration, congested states or acute pulmonary oedema, especially in patients with cardiovascular disease and in patients receiving corticosteroids or corticotropin or drugs that may give rise to sodium retention. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentration. Infusion of > 1 L of isotonic (0.9%) sodium chloride may supply more sodium and chloride than normally found in serum, resulting in hypernatraemia; this may cause loss of bicarbonate ions, resulting in an acidifying effect. Infusion during or immediately after surgery may result in excessive sodium retention.
Surgical patients should seldom receive salt-containing solutions immediately following surgery unless factors producing salt depletion are present. Because of renal retention of salt during surgery, additional electrolyte given IV may result in fluid retention, odema and overloading of the circulation.
Absorption: Irrigation fluids enter the systemic circulation in relatively large volumes and must be regarded as a systemic drug. Absorption of large amounts can cause fluid solute overload, resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary oedema.
Continuous irrigation: Observe caution when solution is used for continuous irrigation or allowed to "dwell" inside body cavities because of possible absorption into the blood stream and circulatory overload.

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Precautions
Clinical supervision should include regular checks of serum electrolytes, acid-base balance and water balance. Caution must be exercised in the administration of Sodium Chloride intravenous Infusion BP to patients receiving corticosteroids or corticotropin.
Pregnancy: Category C
Animal reproduction studies have not been conducted with Sodium Chloride Intravenous infusion BP. It is also not known whether Sodium Chloride Intravenous infusion BP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Intravenous infusion BP should be given to a pregnant woman only if clearly needed.
Do not administer unless solution is clear and seal is intact.
No other medication or substance should be added to this solution unless it is known to be compatible.
Extraordinary electrolyte losses (e.g. during protracted nasogastric suction, vomiting, diarrhea, GI fistula drainage) may necessitate additional electrolyte supplementation. Supply additional essential electrolyte, minerals and vitamins as needed.
Hypokalaemia may result from excessive administration of potassium-free solutions.
If to be administered S.C (as dissolvent and carrier), be aware that any additions to the isotonic Normal Saline solution could render it hypertonic and thus cause pain at the injection site.

Undesirable effects
During infusion, hypernatraemia and hyperchloraemia may occur.
Reactions, which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolaemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic counter-measures and save the remainder of the fluid for examination if deemed necessary.
Postoperative salt intolerance: Symptoms include cellular dehydration, weakness, disorientation, anorexia, nausea, distention, deep respiration, oliguria, increased BUN.

Overdosage
Parenteral preparations are unlikely to pose a threat of Sodium Chloride or fluid overload except possibly in newborn or very small infants. If these occur, reevaluate the patient and institute appropriate corrective measures.

Expiry date
Do not store beyond the expiry date stated on the labeling.

Shelf life
36 months

Storage
Do not store above 25°C.

Presentation
50 ml, 100 ml, 250 ml, LDPE containers.

License number
137-50-30585

Manufacturer
B. Braun Melsungen AG
D-34209 Melsungen

License Holder
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