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Directions for Use

B. Braun Melsungen AG
D-34209 Melsungen, Germany

0.9% w/v Sodium Chloride and 5% w/v Glucose intravenous Infusion BP

Composition

Each 1000ml contains:	
Sodium Chloride	9.0 g
Glucose Monohydrate	55.0 g
Water for Injections to	1000 ml
Electrolytes:	
Sodium	154 mmol/l
Chloride	154 mmol/l
Caloric value:	835 kJ/l ≙ 200 kcal/l
Osmolarity:	585 mOsm/l

Indications
Dehydration,
Sodium and chloride depletion,
Caloric supply.

Contraindications
None known.

Warnings
General:
Note: Dispensing without Doctor's prescription is prohibited.
The administration of intravenous injections can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.
Excessive administration of potassium-free solutions may result in significant hypokalemia.

In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.
Solutions containing dextrose should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.
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 Sodium Chloride Injections may result in sodium retention.

Use in Pregnancy
Animal reproduction studies not been conducted. It is also not known whether these solutions can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity.
Therefore, these solutions should be given to a pregnant woman only of clearly needed.

Use in Pediatrics
For solutions containing Dextrose:
These products should be used with caution in infants of diabetic mothers, except as may be indicated in hypoglycemic neonates.

Adverse Reactions
General:
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection,

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venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. Nausea, fever, and flushing of the skin have occurred.
If an adverse reaction does occur, the infusions should be discontinued, the patient evaluated, appropriate therapeutic countermeasures instituted, and the remainder of the fluid saved for examination if deemed necessary.

Precautions
General:
Do not administer unless the solution is clear and the seal is intact.
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 should be exercised in the administration of parenteral fluids, especially those containing dextrose, sodium ions, to patients receiving corticosteroids or corticotrophin.
Caution should be exercised in the administration of these injections to the very young and to elderly patients.
Administer so that extravasation does not occur. If thrombosis occurs during administration, stop injection and correct.
Solutions containing dextrose should be used with caution in patients with overt or subclinical diabetes mellitus, or carbohydrate intolerance.
Hyperglycemia and glycosuria may be functions of rate of administration or metabolic insufficiency. To minimize these conditions, slow the infusion rate, monitor blood and urine glucose; if necessary, administer insulin.
Vitamin B-complex deficiency may occur with dextrose administration.

Dosage and Administration
Note: Do not administer unless solution is clear and seal is intact.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions where possible.
The dosage is usually dependent upon the age, weight and clinical condition of the patient, as well as laboratory determinations.
Maximum recommended dose: 40 ml per kg body weight and per day.

Flow rate:
Up to 7 ml per kg body weight per hour, or up to 150 drops/min, corresponding to 450 ml/h.

Children:
According to individual requirements.

Overdosage
In the event of fluid or solute overload during parenteral fluids, reevaluate the patient's condition and institute appropriate corrective treatment.

Storage
Do not store above 25 °C.

Presentation
500 ml and 1000 ml Ecoflac® plus containers.

License number
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Importer:
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