

1.4.3 PIL

0.9% Sodium Chloride Intravenous Infusion

Product Name: 0.9% Sodium Chloride Intravenous Infusion

Main ingredients and chemical name: Sodium Chloride

Structural formula: NaCl

Molecular formula : NaCl

Molecular weight: 58.44

【Character】 The product is a colorless clear liquid, with salt flavor.

【Pharmacology and toxicity】

Sodium chloride is an electrolysis supplement agent; sodium and chloride are important electrolysis for the human body and mainly exist in extracellular fluid, which play an important role in maintaining normal volume of blood and extracellular fluid and osmosis pressure. Normal serum sodium concentration is about 135 ~ 145mmol/L, with a 92 percent of the plasma cation and a 90 percent of total osmosis pressure, so the quantity of plasma sodium play a decisive role for the osmosis pressure; normal serum chloride concentration is about 98 ~ 106mmol/L; sodium and chloride in human body are mainly adjusted by hypothalamus, lobus posterior hypophyseos and kidney so as to maintain the stability of body fluid volume and osmosis pressure.

【Pharmacokinetics】

Sodium chloride enter the blood circulation directly after injected by intravenous, and distribute widely in the human body, and mainly exist in extracellular fluid. Both sodium and chloride can be filtrated by glomerule, and partially be absorbed by renal tubules. Sodium chloride is mainly excreted through urine by kidney, some is excreted through sweat.

【Indications】

It is indicated for dehydration caused by all kinds of cases, including hyposmolality, isotonia and hypertonicity; also for the coma caused by hypertonicity non-ketosis diabetes as the administration of isotonia and hyposmolality sodium chloride can correct the dehydration and hyperosmotic state; it is also indicated for low-chloride metabolic alkali poisoning; and external use sodium chloride can be used to wash the eyes and wounds; it also can be used for the induction of labor with water bag.

【Dosage and administration】

1. For hypertonicity dehydration, osmosis concentration of cerebral and cerebrospinal fluid will decrease, if the sodium concentration and osmosis concentration of plasma and cerebral extracellular fluid was decreased fleetly, cerebral edema may happen. In the usual case, at the beginning 48 hours of treatment, the reducing speed of plasma sodium concentration should not exceeding 0.5mmol/L.

If the patients was in shock, sodium chloride injection should be administered at first, at the same time colloid can be supplied on demand; after recovery from shock, plasma sodium > 155mmol/L, plasma osmosis concentration > 350mOsm/L, 0.6% hypotonicity sodium chloride injection can be administered. Awaiting the plasma osmosis concentration < 330mOsm/L, 0.9% sodium chloride can be used. The total amount of supplement fluid can be estimated by the following formula for the reference:

$$\text{supplement fluid amount (L)} = \frac{[\text{plasma sodium concentration (mmol/L)} - 142]}{\text{plasma sodium concentration (mmol/L)}} \times 0.6 \times \text{weight (Kg)}$$

Usually at the first day half dose is administered, the remains is administered during the later 2 ~ 3 days. In the clinical experiments the dosage can be adjusted according to cardio-pulmonary function.

2. For isotonia dehydration, isotonia injection should be administered in principle, such as 0.9% sodium chloride injection or compound sodium chloride injection. But for the aforementioned injection, chloride concentration is obviously higher than plasma, and the single administration of sodium chloride may lead to hyperchloremia, thus 0.9% sodium chloride had better be administered combined with 1.25% sodium bicarbonate or 1.86% (1/6M) sodium lactate with a proportion of 7:3 after they are prepared. The latter concentration is about 107 mmol/L, which can reduce the chloride concentration and correct metabolic acidosis. The supplement amount could be estimated according to weight or packed cell volume. ① Estimated as per weight, supplement fluid amount (L) = (weight reduction (kg) × 142) / 154; ② Estimated as per packed cell volume: supplement fluid amount (L) = (actual packed cell volume - normal packed cell volume × weight (kg) × 0.2) / normal packed cell volume. Normal packed cell volume of male is 48%, and that of female is about 42%.

3. For hyposmolality dehydration: when serious hyposmolality dehydration happen, solute in the cerebral cell is reduced to maintain the cell volume. If the sodium concentration and osmosis concentration in plasma and extracellular fluid was increased fleetly, that may lead to cerebral cell trauma. In the usual cases, when the plasma sodium is lower than 120mmol/L, the increasing speed of plasma sodium should keep 0.5mmol/L, not exceeding 1.5 mmol/L.

When the plasma sodium is lower than 120 mmol/L or central nervous system symptom happen, 3% ~ 5% sodium chloride injection can be administered by slow drip. Commonly within 6 hours plasma sodium concentration will

be increased to over 120 mmol/L. sodium-supplement amount (mmol/L) = $\frac{1}{\text{plasma sodium concentration (mmol/L)}} \times [\text{plasma sodium concentration (mmol/L)} - \text{actual plasma sodium concentration (mmol/L)}] \times \text{weight (kg)} \times 0.2$. After plasma sodium concentration rise again to over 120 ~ 125mmol/L, the treatment can be changed to use isotonia solution or isotonia solution combined with hypertonicity glucose injection or 10% sodium chloride injection.

4. For low chloride alkali poisoning: Firstly 0.9% sodium chloride injection or compound sodium chloride injection is administered with the dose 500 ~ 1000ml, then determine the dose as per the alkali poisoning state.

5. For external use, normal saline solution can be used to wash the wound and eyes.

【Side-effect】

(1) Overdose and over-rapidness of infusion may lead to retention of water and sodium, cause hydrops, increased blood pressure, increased heart rate, oppressed feeling in chest, breath hard, even left ventricular failure.

(2) Overdose and over-rapidness of injection low-concentration sodium chloride may lead to haemolysis, cerebral edema and so on.

【Contraindication】

- (1) diabetes ketosis acidose;
- (2) hyperglycemia non-ketosis hyperosmotic state;

【Attention】

(1) Avoid using the medicine for the following cases: ① hydropsy, such as the kidney syndrome, liver cirrhosis, hydroperitoneum, congestive heart-failure, acute left ventricular failure, hydrocephalus, idiopathic edema and etc.; ② acute kidney failure oliguria stage, chronic kidney failure decreased urine and bad reaction for diuretic; ③ hepertension; ④ hepoto-potassium.

(2) According to the clinical requirements, examine the concentration of sodium, potassium, chloride in the serum; examine acid and alkali concentration equality index; examine the renal function, blood pressure and cardio-pulmonary function.

【Pregnancy and Lactation】

Forbid to use the sodium chloride injection for the patients with hypertension of pregnancy syndrome.

【Pediatric Use】 The dosage and the speed should be controlled strictly.

【Geratology】 The dosage and the speed by drip should be controlled strictly.

【Interaction】 Pay attention to the incompatibility of drugs when Sodium Chloride Injection used as solvent or dilution.

【Overdose】 Overdose may lead to hypernatremia and hypo potassium, also may lead to the missing of bicarbonate.

【Specification】 500ml: 4.5g;

【Storage Condition】 Store below 25 ℃. Protect from sunlight. Keep out of reach of children

【Package】 500mL PP bottle

【Expiry date】 3 years

【Manufacturer】

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