1.4 Product information

1.4.1 Summary of Product Characteristics

Summary of 0.9% Sodium Chloride Injection

1. Name of the product

0.9% Sodium chloride injection

2. Qualitative and quantitative composition

Sodium chloride: 9.0g/ L

Each ml of the solution contains 9mg of sodium chloride

Mmol / L: Na^+: 154 Cl^-: 154

3. Pharmaceutical form

Solution for intravenous infusion

Clear solution, free of visible particles

4. Clinical particulars

4.1 Therapeutic indications:

Sodium Chloride 0.9% intravenous infusion is indicated for:

Treatment of isotonic extracellular dehydration

Treatment of sodium depletion

Vehicle or diluent of compatible drugs for parenteral administration

4.2 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:

[Plasma sodium concentration (mmol/L) -142]

Supplement fluid amount (L)

=----------*0.6*weight (Kg)

Plasma sodium concentration (mmol/L)

Usually at the first day half dose is administered, the remains are 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 107mmol/L, and it could reduce the chloride concentration and correct metabolic acidosis. The supplement amount could be estimated according to weight or packed cell volume. ①estimated as per weight, supplement fluid amount (L) = (weight reduction (kg) ×142)/154; ②estimated 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 hypoosmolality dehydration: when serious hypoosmolality dehydration happens, 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 1.5mmol/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) = [142－actual plasma sodium concentration (mmol/L)] ×weight (kg) ×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.

Route of administration: the solution is used for administration by intravenous infusion.

4.3 Contraindications:

The solution is contra-indicated in patient presenting hypernatremia or hyperchloraemia.

The contra-indications related to the added medicinal product should be considered

4.4 Warnings and precautions:

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

4.5 Pregnancy and Lactation:

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

4.6 Interaction

Pay attention to the incompatibility of drugs, when sodium chloride injection is used as solvent or dilution.Side-effect

4.7 Side effects

(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.

4.8 Overdose

General adverse effects of sodium excess in the body include nausea, vomiting, diarrhea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death.

An excessive volume of Sodium Chloride 0.9% may lead to hypernatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death) and sodium overload (which can lead to central and/or peripheral oedema) and should be treated by an attending specialised physician.

Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

When Sodium Chloride 0.9% is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

5. Pharmacological properties

5.1 Pharmacodynamic property

Pharmacotherapeutic group: “Other IV Solution Additives”

ATC code: B05XA03

Sodium Chloride 0.9% intravenous infusion is an isotonic solution, with an approximate osmolarity of 308 mOsm/l.

The pharmacodynamic properties of the solution are those of the sodium and chloride ions in maintaining the fluid and electrolyte balance. Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

5.2 Pharmacokinetic properties

Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption.

Small amounts of sodium are lost in the faeces and sweat.

5.3 Preclinical safety data

The safety of sodium chloride in animals is not relevant in view of its presence as a normal component in animal and human plasma.

6. Pharmaceutical particulars

6.1 List of excipients

Water for injections

6.2 Incompatibilities

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products. Those additives known to be incompatible should not be used

6.3 Shelf life

Expiry date during use: Additive drugs

The chemical and natural stability of any additive drug at the pH of Sodium Chloride 0,9% solution for intravenous infusion in the container, should be checked before use.

The diluted solution should be used immediately in order to avoid microbial exposure, unless the dilution is performed under controlled and established aseptic conditions. If not used immediately, the storage time and condition before use is up to the user's responsibility.

Three years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Package sizes: 100, 250, 500 and 1000 ml in PP bottles

6.6 Special precautions for disposal and other handling

Before adding a drug, verify it is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution. Additives may be introduced before infusion or during infusion through the injection site.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.

When additive is used, verify isotonicity prior to parenteral administration.

Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

Opening

• Remove the container from the package just before use.

• Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired

• Check solution for limpidity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution.

Preparation for administration

Use sterile material for preparation and administration.

• Suspend container from eyelet support.

• Remove plastic protector from outlet port at bottom of container:

• Use an aseptic method to set up the infusion.

• Attach administration set. Refer to directions of the accompanying set for connection, priming of the set and administration of the solution..

Techniques for injection of additive medications

Warning: Additives may be incompatible.

To add medication before administration

• Disinfect medication site.

• Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.

• Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration

• Close clamp on the set

• Disinfect medication site.

• Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.

• Remove container from IV pole and/or turn to an upright position.

• Evacuate both ports by tapping gently while the container is in an upright position.

• Mix solution and medication thoroughly.

• Return container to in use position, re-open the clamp and continue administration.

7. Marketing authorisation holder

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