

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Sodium Chloride 0.9% w/v Injection BP.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml of solution contains 9 mg of Sodium Chloride.

For excipients, see 6.1

### **3 PHARMACEUTICAL FORM**

Solution for Injection.

Clear, colourless, sterile solution.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

1. In the reconstitution, dilution and making up of certain drugs.

2. As a saline irrigant.

3. As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

#### **4.2 Posology and method of administration**

Route of administration: For parenteral administration, or as appropriate to the reconstituted drug.

Dosage:

The volume given and administration rate depends on the additive.

#### **4.3 Contraindications**

None known when used as a diluent or priming solution.

#### **4.4 Special warnings and precautions for use**

Sodium Chloride 0.9%w/v Injection BP should be administered with caution to patients with congestive cardiac failure, pre-eclampsia, impaired renal function or oedema with sodium retention.

Care is also required when administering this solution to very young or to the elderly patients.

Pseudohyponatraemia is a condition in which spuriously low concentrations of sodium are found when plasma sodium is measured by conventional methods. It may occur when there is an abnormally high concentration of large molecules and hence an abnormally low percentage of plasma water. This may occur in hyperlipaemia and hyperproteinaemia and has also been reported in patients with diabetes mellitus. Correct values may be obtained by referring the concentration to plasma water.

Before use, ensure that the container is undamaged and the contents clear in appearance. After use, discard any remaining solution.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known when used as a diluent or priming solution.

#### **4.6 Pregnancy and lactation**

The solution is physiological saline and may be used during pregnancy and lactation.

#### **4.7 Effects on ability to drive and use machines**

None known.

#### **4.8 Undesirable effects**

Injudicious intravenous saline therapy (e.g. post-operatively and in patients with impaired cardiac or renal function) may cause hypernatraemia. Osmotically induced water shift decreases intracellular volume, resulting in dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage.

General adverse effects of sodium chloride excess in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivary and lachrymal secretions, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate, with an acidifying effect. With judicious use of intravenous saline therapy, these side effects can be avoided.

If administered sub-cutaneously, any addition to the isotonic solution could render it hypertonic and cause pain at the site of injection.

When used as a diluent any undesirable effects may be related to the additive.

#### **4.9 Overdose**

Overdose is very unlikely as vials contain a maximum of 10ml.

Because the infusion is iso-osmotic with plasma, administration of an excessive volume of Sodium Chloride Intravenous Infusion 0.9% w/v produces an isotonic expansion of the extracellular fluid compartment which may result in oedema. The concentration of sodium in plasma is usually normal. Hypernatraemia may occur when patients who are dependent on parenteral fluids are given isotonic saline without free water to replace daily water loss through the skin. Irritability, lethargy and weakness are early neurologic signs of acute hypernatraemia. Osmotically-induced water shifts decrease the intracellular fluid volume and result in dehydration of internal organs; cerebral dehydration may provoke convulsive activity and may lead to coma and death. With judicious use of intravenous saline therapy, these effects can be avoided.

Diuretics may be used to treat oedema resulting from isotonic expansion, and appropriate replacement therapy should be employed to avoid fluid and electrolyte imbalance. Treatment of hypervolaemic hypernatraemia requires removal of sodium in excess of water and can be achieved by replacing diuretic-induced sodium and water losses with only water. The basic aim of therapy is to restore the volume and composition of the body fluids to normal.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Sodium Chloride Intravenous Infusion 0.9% w/v is a sterile solution of physiological saline containing approximately 150 mmol of sodium and chloride per litre.

### **5.2 Pharmacokinetic properties**

Sodium chloride is well absorbed from the gastro-intestinal tract. Sodium is predominantly excreted via the kidneys and renal reabsorption of sodium is extensive. Small amounts of sodium are excreted in the faeces and in sweat.

### **5.3 Preclinical safety data**

No relevant information other than that which is shown in other sections of the Summary of Product Characteristics.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Water for injections.

### **6.2 Incompatibilities**

The addition of sodium chloride to mannitol 20% or 25% may cause precipitation of the mannitol. Do not add any other agent to this solution unless compatibility is known.

### **6.3 Shelf life**

2 years.

Use immediately after first opening of the ampoule. Discard unused contents.

#### **6.4 Special precautions for storage**

Do not store above 25°C.

Do not refrigerate.

#### **6.5 Nature and contents of container**

5 ml or 10 ml hermetically sealed translucent plastic ampoules, polyethylene Ph. Eur. packed in cardboard cartons to contain 10 or 100 ampoules.

#### **6.6 Special precautions for disposal**

If only part of the ampoule is used, discard the remaining solution.

### **7 MARKETING AUTHORISATION HOLDER**

Antigen International Ltd.

Roscrea

County Tipperary

Ireland.

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 02848/0227

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

31/08/2007

**10 DATE OF REVISION OF THE TEXT**

21/09/2010