



## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **PRODUCT SUMMARY**

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

Sodium Chloride Injection BP 0.9% w/v

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

Each ml contains 0.9% Sodium Chloride in Water for Injections.

#### **3. PHARMACEUTICAL FORM**

Sterile Injection.

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

For use in prophylactic and replacement therapy, requiring the use of isotonic saline solution.

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

As a saline irrigant.

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

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

In the prophylaxis or replacement therapy of extracellular fluid deficits, the dosage of sodium chloride injection BP 0.9% is dependent on the age, weight, clinical status and degree of deficiency, and must be determined on the individual basis.

##### **4.3 Contra-indications**

There are no absolute contraindications to use of Sodium Chloride Injection BP 0.9% w/v.

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

Sodium Chloride Injection BP 0.9% w/v, 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 with administering this solution to very young or to 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 Interactions with other medicinal products and other forms of interactions**

Concomitant administration of other sodium salts, may contribute to the sodium load. Only use as a pharmaceutical diluent where indicated in the manufacturer's literature.

#### **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-operative 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.

## **4.9 Overdose**

Injudicious intravenous saline therapy (e.g. post-operatively or 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.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

The principal determinant of the effective osmolality of the extracellular fluids (and also of the intracellular fluids, since they remain in osmotic equilibrium with the extracellular fluids) is the extracellular fluid sodium concentration. The reason for this is that sodium is the most abundant positive ion of the extracellular fluid. Negative ion concentrations of the body fluids are adjusted to equal those of the positive ions by renal acid-base control mechanisms. Furthermore, glucose and urea, the most abundant of the non-ionic osmolar solutes in extracellular fluids, normally only represent about 3% of the total osmolality. Therefore, in effect, the extracellular fluid sodium ion concentration controls over 90% of the effective osmotic pressure of the extracellular fluid. Sodium Chloride remains the most important single salt for prophylaxis or replacement therapy of deficits of extracellular fluid. Volume contraction, whether isotonic, hypotonic or hypertonic, may seriously impair the circulation (cardiac output falls and microcirculation is compromised) and prompt infusion of isotonic sodium chloride solution is indicated.

### **5.2 Pharmacokinetic properties**

The homeostatic mechanisms involved in maintaining constant ion concentrations are well described in standard text books of physiology and biochemistry and are not, therefore, included here.

### **5.3 Preclinical safety data**

No further information other than that which is included in the Summary of Product Characteristics.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Water for Injections  
Sodium Hydroxide  
Hydrochloric Acid

### **6.2 Incompatibilities**

The addition of sodium chloride to mannitol 20 or 25% may cause precipitation of the mannitol.

### **6.3 Shelf life**

60 months for ampoules.  
36 months for vials.

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

Should be stored at room temperature and protected from excessive heat and freezing.

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

Type I clear glass ampoules, 2ml, 5ml, 10ml and 20ml. Packed in cardboard cartons to contain 10 ampoules.

Type I clear glass vials 50ml with chlorbutyl rubber stopper, plastic outer cap and inner aluminium ring.

Type II clear glass vials (33ml, 100ml and 200ml) with bromobutyl rubber stopper, plastic outer cap and inner aluminium ring.

### **6.6 Instructions for use, handling and disposal**

Use as directed by a physician.

## **ADMINISTRATIVE DATA**

## **7. MARKETING AUTHORISATION HOLDER**

hameln pharmaceuticals ltd  
Gloucester  
UK

## **8. MARKETING AUTHORISATION NUMBER**

1502 / 0006R

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

30th August 1985/ 10th January 1995

**10. DATE OF (PARTIAL) REVISION OF TEXT**

25/01/2010