

# **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Saline Nebuliser Solution  
(Sodium Chloride 0.9% w/v)

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml of solution contains 9 mg of Sodium Chloride

For a full list of excipients see section 6.1

## **3 PHARMACEUTICAL FORM**

Solution for nebulisation

Clear, colourless solution in a clear, plastic single dose ampoule

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For dilution of solutions for nebulisation.

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

Adults, children and elderly: use as directed by the physician.

Saline Nebuliser Solution is only to be used as a diluent for diluting products for nebulisation and should not be used on its own. It should not be taken orally or administered parenterally.

Each ampoule contains 2.5 ml of solution.

Refer to the patient information leaflet of the nebulised product to be diluted that your physician has prescribed you for detailed instructions on use of this solution as a diluent. To ensure accurate dosing it is recommended that a dosing syringe is used if necessary.

**Method of Administration:** By inhalation from a suitable nebuliser or an intermittent positive pressure ventilator after the single dose ampoule has been opened and its contents transferred to the nebuliser chamber. Administration should be in accordance with the manufacturer's instructions for the device.

1. Prepare the nebuliser by following the manufacturer's instructions and the advice of your doctor.
2. The nebulised product to be diluted should be introduced into the nebuliser chamber as instructed in the appropriate patient information leaflet.
3. Carefully separate a new saline ampoule from the strip. Never use an ampoule that has been opened already.
3. Open the ampoule by simply twisting off the top, always taking care to hold it in an upright position.
4. Squeeze the contents of the plastic ampoule or use a dosing syringe as required into the nebuliser chamber and swirl gently to mix.
5. Assemble the nebuliser and use it as directed by your doctor.
6. After nebulisation, clean the nebuliser according to the manufacturer's instructions. It is important that the nebuliser is kept clean.

As the single dose units contain no preservatives it is important that the contents are used immediately after opening and a fresh ampoule is used for each administration to avoid microbial contamination. Partly used, opened or damaged single dose units should be discarded.

Any solution remaining in the nebuliser chamber should be discarded.

### **4.3 Contraindications**

The solution should not be administered orally or parenterally.

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

Do not use unless the product is clear and the pack intact. Discard any surplus after use. Saline Nebuliser Solution should be used with a nebuliser, only under the direction of a physician. Patients using nebuliser solutions at home should be warned that if the usual relief is diminished or the usual duration of action reduced, they should consult their doctor.

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

Not known.

#### **4.6 Fertility, Pregnancy and lactation**

As with most medicines, consult your doctor first if you are pregnant or breastfeeding.

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

Not known.

#### **4.8 Undesirable effects**

Saline Nebuliser Solution is not expected to cause any undesirable effects in normal use.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme; website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

#### **4.9 Overdose**

Substantial oral ingestion may require the use of a diuretic to remove excess sodium.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Isotonic (0.9% w/v) sodium chloride solution is widely used for dilution purposes.

## **5.2 Pharmacokinetic properties**

Not applicable

## **5.3 Preclinical safety data**

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SPC. Please refer to the product to be reconstituted.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Water for Injections

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf life**

24 months

Ampoules removed from the foil overwrap should be used within 90 days.

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

## **6.4 Special precautions for storage**

Do not store above 25°C.  
Do not refrigerate or freeze.

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

A unit dose blow moulded hermetically sealed low density polyethylene ampoule containing 2.5 ml of solution. Strips of ten ampoules are overwrapped in an aluminium laminate foil pack. Saline Nebuliser Solution is available in boxes containing 20, 60 or 100 ampoules.

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

No special requirements.

### **7 MARKETING AUTHORISATION HOLDER**

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

PL 20075/1089

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

23/10/2009

**10 DATE OF REVISION OF THE TEXT**

11/09/2018