

# **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Saline Steri-Neb 0.9% w/v

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ampoule contains 0.9% w/v solution of sodium chloride.

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Solution for nebulisation

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For dilution of solutions for nebulisation.

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

#### Posology

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

#### Method of administration

By inhalation from a suitable nebuliser.

For instructions on dilution of the medicinal product before administration, see section 6.6.

### **4.3 Contraindications**

Not applicable.

**4.4 Special warnings and precautions for use**

Not applicable.

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

Not applicable.

**4.6 Fertility, pregnancy and lactation**

Not applicable.

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

Not applicable.

**4.8 Undesirable effects**

Not applicable.

**4.9. Overdose**

Not applicable.

**5 PHARMACOLOGICAL PROPERTIES**

**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**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Water for injections

### **6.2. Incompatibilities**

Not applicable

### **6.3 Shelf life**

2 years

### **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 3ml ampoule containing 2.5 ml of a clear, colourless to light yellow aqueous solution. Strips of 5 Steri-Neb are packed into foil laminate pouches, which in turn are packed into boxes containing 20 and 100 (Steri-Neb).

### **6.6 Special precautions for disposal and other handling**

Saline Steri-Neb is for the dilution of solutions for nebulisation.

Only use Saline Steri-Neb in a nebuliser. Do not swallow the solution or use it in injections.

- Prepare the nebuliser for use according to the manufacturer's instructions
- Empty the solution that needs diluting into the nebuliser following the manufacturer's instructions
- Remove a Steri-Neb from the labelled strip by twisting and pulling
- Hold the Steri-Neb upright and twist off the cap

- Squeeze the contents into the reservoir of the nebuliser.
- Following the manufacturer's instructions, use the nebuliser
- After using the nebuliser, throw away any solution that is left in the reservoir
- Clean the nebuliser thoroughly
- Discard any unused portion of Saline Steri-Neb.

## **7      MARKETING AUTHORISATION HOLDER**

Norton Healthcare Limited T/A IVAX Pharmaceuticals UK  
Ridings Point  
Whistler Drive  
Castleford  
West Yorkshire  
WF10 5HX  
United Kingdom

## **8.      MARKETING AUTHORISATION NUMBER**

PL 00530/0691

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

1 January 2004

## **10     DATE OF REVISION OF THE TEXT**

08/06/2021