Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Saline Steri-Neb 0.9% w/v Nebuliser Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Steri-Neb unit containing 2.5ml of solution contains 0.9%w/v sodium chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nebuliser Solution
Clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the dilution of solutions for nebulisation.

4.2 Posology and method of administration

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

Route of Administration

The solution to be diluted should be emptied into nebuliser following the manufacturer's instructions. The prescribed amount of sodium chloride solution is added to the nebuliser. The whole solution is then administered from a power-operated nebuliser at an adequate flow rate, via a face mask or mouthpiece.

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 interactions

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.

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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Not applicable.

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

Unopened: 2 years
Once opened: Use immediately. Discard any unused portion.

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 plastic ampoule containing 2.5 ml of a clear, colourless solution. Saline Steri-Neb is available in boxes containing 20 and 100 ampoules (packed into foil laminate pouches, containing strips of 5x Steri-Nebs per pouch).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Saline Steri-Neb is for the dilution of solutions for nebulisation. It should be administered from a power operated nebuliser via a facemask or mouthpiece.

Do not use Saline Steri-Neb if you notice the solution is cloudy.

For single use only. Any content of the product remaining after use should be discarded.

7 MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/087/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 February 1994

Date of last renewal: 18 February 2009

10 DATE OF REVISION OF THE TEXT

June 2022