

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 special 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

5.1 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 containers

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-Nebs are packed into foil laminate pouches, which in turn are packed into boxes containing 20 and 100 (Steri-Nebs).

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

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8. MARKETING AUTHORISATION NUMBER

PL 00530/0691

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

1 January 2004

10. DATE OF REVISION OF THE TEXT

08/06/2021