Summary of Product Characteristics

1. Name of Product

Resp-Ease 7%

2. Qualitative and Quantitative Composition

Sodium Chloride 7g
Purified Water QS 100ml
Preservative Free

3. Pharmaceutical Form

Solution for nebulisation. Clear, colourless solution in a clear, plastic single dose vial.

4. Clinical Particulars

4.1. Therapeutic Indications

Resp-Ease is a sterile 7% saline solution for inhalation. Resp-Ease increases the mobilisation of secretions in the lower respiratory tract by osmotic effects and prevents drying of bronchial mucous.

4.2. Posology and Method of Administration

Adults, children and elderly: use as directed by the physician. Resp-Ease 7% is only to be used on its own. It should not be taken orally or administered parenterally. Each vial contains 4 ml of solution.

Method of Administration: By inhalation from a suitable nebuliser or an intermittent positive pressure ventilator after the single dose vial has been opened and its contents transferred to the nebuliser chamber. Administration should be in accordance with the manufacturer's instructions for the device. Prepare the nebuliser by following the manufacturer's instructions and the advice of your doctor. Carefully separate a new saline vial from the strip. Never use a vial that has been opened already. Open the vial by simply twisting off the top, always taking care to hold it in an upright position. Squeeze the contents of the plastic ampoule or use a dosing syringe as required into the nebuliser chamber. Assemble the nebuliser and use it as directed by your doctor. 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 vial 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. Resp-Ease 7% 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. Interactions 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

Resp-Ease 7% 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

4.9. Overdose

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

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

Hypertonic (7% w/v) sodium chloride solution is widely used for its osmotic effects.

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.

6. Pharmaceutical Properties

6.1. List of Excipients

Purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

24 months. Use immediately after first opening of the vial. 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 vial containing 4 ml of solution. Strips of ten vials. Resp-Ease 7% is available in boxes containing 60 vials.

6.6. Special Precautions for Disposal and Other Handling

No special requirements.

7. Marketing Authorisation Holder

Resp-Ease 7% is a Medical Device certified in accordance with EU Directive 93/42/EEC, as amended.

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8. Marketing Authorisation Number(s)

Not applicable.

9. Date of First Authorisation/Renewal of Authorisation

20/03/2015

10. Date of Revision of The Text

22/01/2016

11. Dosimetry

Not applicable.

12. Instructions for Preparation of Radiopharmaceuticals

Not applicable.

13. Legal Category

Medical Device.