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INSTRUCTIONS FOR USE

65NOT2118/A



STERILE HYPERTONIC SOLUTION OF SODIUM CHLORIDE 6% IN VIALS FOR INHALATION



Indications:

Increases the mobilisation of secretions in the lower respiratory track by osmotic effects, for example in case of cystic fibrosis, bronchiectasis, bronchiolitis.

Prevents drying of bronchial mucous.

This hypertonic saline solution 6% for inhalation can be used with pneumatic or ultrasonic nebulizers.

Forms and presentations:

Pack of 48 single dose vials of 4mL

Composition:

Sodium chloride: 6g Purified water qs 100 mL Preservative free

Directions for use:

The recommended dose of Hypertonic saline solution 6% for inhalation is one unit-dose vial 2 to 4 times a day.

Break off a unit-dose vial and open it by twisting off the top.

Pour the inhalation solution into the nebulizer.

Use your nebulizer according to the manufacturer's instructions provided with the system.

Side effects:

In rare case, temporary irritations (e.g. coughing) or reversible constriction of the bronchia can occur. Pretreatment with bronchodilatory medication is recommended. If undesirable side effects do occur, discontinue treatment and seek advice from your doctor or pharmacist.



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Precautions for use:

Single use only

Strictly reserved to inhalation.

Not for injection.

Check that unit-dose vial has not been damaged prior to use. Do not use a damaged unit-dose vial.

Follow the nebulizer manufacturer's instructions for use.

If a tendency to develop dyspnea or hypersensitivity is present, the inhalation solution must not be used without medical supervision.

Do not mix with other medication.

Keep out of the reach of children.

Do not use after expiry date.

Opened single-dose vials must not be used: since the product does not contain preservatives a re-use would lead to the risk of administration of a contaminated solution.

The hypertonic saline solution 7% for inhalation is a class lla medical device.

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Version of instructions for use: 02/2014.

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