



Patient Information Leaflet

PulmoClear[®]

Sterile 6% Hypertonic Sodium Chloride Solution

FOR INHALATION ONLY

NOT FOR INJECTION

PRESERVATIVE FREE

6%



60 vials x 4ml

Indications:

Increases the mobilisation of secretions in the lower respiratory tract by osmotic effects (for example in cases of cystic fibrosis, bronchiectasis, bronchiolitis). Prevents drying of bronchial mucous. This hypertonic saline solution 6% for inhalation can be used with pneumatic or ultrasonic nebulisers.

Forms and presentations:

Pack of 60 single-dose vials of 4ml

Composition:

Sodium Chloride: 6 g, 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 nebuliser. Use your nebuliser according to the manufacturer's instructions provided with the system.

Side effects:

In rare cases, 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.

Precaution for use:

Single use only. Strictly reserved to inhalation. Not for injection. Check that the unit-dose vial has not been damaged prior to use. Do not use a damaged unit-dose vial. Follow the nebuliser 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 medications.

Keep out of the reach of children.

Do not use after the expiry date.

Opened single-dose vials must not be reused: 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 6% for inhalation is a Class IIa medical device.

Date of CE marking: 27/02/2014.

Version of the instructions for use: 02/2014.

Explanation of symbols:



Use by date



Lot no.



Please follow the instructions for use.



for single use



Manufacturer



Sterilized using aseptic processing techniques



Product is in conformity with the applicable requirements of European legislation



Not for injection

Distributed by:



Trion Pharma UK,

Cowplain PO8 8DL

TriOn Pharma Info@trionpharma.co.uk