



Pneumoxytol[®]

MYO-INOSITOL 400 mg

Sterile single-dose preservative-free solution
to be sprayed via nebuliser

CATEGORY: Medical device.

PRODUCT CHARACTERISTICS: Inositol is a polyol known for being an important osmolyte. In fact, it is excellent at binding and withholding significant quantities of water, especially in the tissues of the respiratory tract. This lubricating and emollient ability is useful for alleviating symptoms associated with inflammation, such as difficulty swallowing, foreign body sensation in the throat, tickling and dryness. Inositol lowers the surface tension of the pulmonary surfactant by improving gas exchange in the alveoli and bronchioles.

INDICATIONS: Recovery and maintenance of the natural physiology of the mucosa and the tissue of the respiratory tract affected by chronic bronchial inflammation, such as asthma and chronic obstructive pulmonary disease (COPD). Recovery and maintenance of the natural physiology of the mucosa and the tissue of the respiratory tract affected by environmental pollutants, cigarette smoke or other chemicals. Pneumoxytol[®] is indicated for the treatment of symptoms relating to illnesses of the upper airways including: acute as well as chronic oropharyngitis, hoarseness and cough caused by post-viral irritation, cold and flu, aftermath of ENT operations. Reduction in respiratory distress syndrome in premature babies. Pneumoxytol[®] is indicated for adults and children. It does not replace, but rather supplements other therapeutic treatments.

COMPOSITION: Each 3 ml ampoule contains: myo-inositol, purified water, sodium chloride.

COMPONENTS	%	3 ml unit dose AMPOULE
Purified water	85.8%	q.s. a 3 ml
Myo-inositol	13.3%	400 mg
Sodium chloride	0.9%	27 mg

FREQUENCY OF USE: It is recommended to take 1 x 3 ml ampoule or as instructed by your doctor, up to a maximum of 3 ampoules per day. Do not exceed the recommended dose.

HOW TO USE: Pneumoxytol[®] is provided in ampoules with pre-broken safety seals. To open the ampoule:

1. hold the ampoule with the tip pointing to the sky;
2. exert slight pressure, fold and break the ampoule at the neck.

Use the contents of one ampoule in a nebuliser for aerosol therapy. It is recommended to use devices with a compressor that guarantees a high output flow (indicative value of at least 0.40 ml/minute). Do not use ultrasound devices.

It is recommended to notify the manufacturer and the competent authority of any serious incident that has occurred in relation to the medical device.



WARNINGS: Do not use this device after the expiry date stated on the pack. Do not use this device if the packaging is open or damaged. Do not re-sterilise. The device is single-use. Do not re-use any residue in the ampoule. Store at T ≤ 25 °C. Do not freeze. Once the ampoule is opened, the product should be used

immediately. Do not use the product for longer than 30 consecutive days. Smoking compromises the protective effect of myo-inositol on bronchial and alveolar function. It is recommended to use Pneumoxytol® after speaking to your doctor. Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority of the Member State in which you are established. Do not swallow. **KEEP OUT OF THE REACH OF CHILDREN.**

INTERACTIONS: There are currently no known interactions between Pneumoxytol® and any concomitant therapies. However, it is recommended to speak to your doctor before using the product in combination with other medical devices and drugs.

CONTRAINDICATIONS AND SIDE EFFECTS: There are currently no known contraindications against the use of Pneumoxytol®, nor have any side effects been reported. However, use of these specific products, especially if prolonged, can cause sensitisation. Should this occur, discontinue treatment and seek medical advice to initiate suitable therapy. If you notice any undesirable effect not listed in this leaflet, inform your doctor or pharmacist.

PREGNANCY AND BREASTFEEDING: This product should not be used during pregnancy or while breastfeeding.

SHELF LIFE AND STORAGE: The expiry date is indicated on the packaging. Do not use after the expiry date indicated on the pack or if the packaging is open or damaged. The expiry date refers to the product in its intact packaging, stored correctly.

PACKAGE

10 ampoules containing 3 ml of spray solution.

DISPOSAL

There are no special requirements to be followed for disposal of the product. Check local regulations in force.

Mechanism of action: Reduction of the surface tension of the pulmonary surfactant in the bronchioles and hydration and lubrication of the mucosa of the respiratory tract.



Leaflet paper PAP22

Recycling - Please check the regulations in your municipality



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