Viscoflu® AMPOULES

Sterile hypertonic saline solution with N-acetylcysteine for nebulizer and for instillation

5 ML AMPOULES

1. IDENTIFICATION, COMPOSITION AND PURPOSE OF THE MD

1.1 DESCRIPTION AND INDICATIONS

Viscoflu® is a single-use medical device indicated during treatment of respiratory diseases featuring dense and viscous hypersecretion.

1.2 CONTRAINDICATIONS AND LIMITATIONS FOR USE

Hypersensitivity to the active ingredients or to any of the excipients.
Viscoflu® is contraindicated in children under 2 years of age.
Viscoflu® should only be administered during pregnancy and breastfeeding if it is absolutely necessary and under the direct supervision of a doctor.

1.3 COMPOSITION

One 5 ml ampoule contains: N-acetylcysteine 300 mg, sodium chloride 150 mg. Excipients: sodium hydroxide, sodium edetate, water for injectable preparations.

1.4 MECHANISM OF ACTION

Viscoflu® thins dense and viscous mucus through the physical/mechanical action of its ingredients:

- sterile buffered hypertonic solution of sodium chloride: hypertonic saline solutions applied directly to a mucus membrane by osmosis draw water from the intracellular to the extracellular compartment. This increases the percentage of water in the mucus lining the epithelium, thinning it and facilitating its removal;
- N-acetylcysteine (NAC): acetylated amino acid cysteine variant, exerts a mucolytic activity by direct contact with the mucus. This activity depends on the presence in the molecule of sulphydryl radicals capable of breaking the disulfide bonds of the mucoproteins that give mucus viscosity, depolymerising it. NAC also has an antioxidant action that helps preserve the tropism of the respiratory epithelia.

2.PACKAGING FORMAT

- wallet containing 5 ampoules of 5 ml each
- wallet containing 10 ampoules of 5 ml each

3. METHOD OF USE

Viscoflu® is a sterile solution that can be:

- nebulized by aerosol dispensers to be inhaled in order to reach the bronchial region;
- directly instilled by ear and nose wash;
- instilled at the endobronchial level through permanent catheters, bronchoscopy, etc.;

3.1 DOSE, METHOD AND TIME OF ADMINISTRATION

Aerosol administration: nebulize one ampoule per session with 1-2 sessions per day over 5-10 days. The frequency and doses of sessions can be modified by the doctor over a wide range with respect to the clinical and therapeutic effect without the need to significantly differentiate the doses for adults or children.
Instillation and ear washing and other cavities: ½ ampoule or 1 ampoule per application.
Endotracheal-bronchial instillations: 1 ampoule per application, 1-2 times per day or according to need.

3.2 OVERDOSE

Excessive doses of **Viscoflu®** by inhalation and endotracheal-bronchial instillation could lead to massive and excessive fluid secretions that, in patients with depression of the cough reflex and expectoration in particular, may make bronchoalveolar lavage necessary.

4. KNOWN SIDE EFFECTS

Due to the high salt concentration of the solution, the use of **Viscoflu®** can induce occasional localised irritation phenomena that can cause bronchospasm, burning sensation in the nasal mucosa, rhinorrhea, nausea, vomiting. Among these effects, the induction of the cough reflex within tolerable limits is to be welcomed as it promotes expectoration and unblocking of airways.The side effects of **Viscoflu®** usually disappear spontaneously by discontinuing treatment. If they do not disappear, consult your doctor. Following the instructions in the leaflet reduces the risk of side effects.

5. KNOWN INTERACTIONS WITH OTHER MEDICAL DEVICES OR DRUGS

In patients treated with nitroglycerin-based drugs it is appropriate to consult a doctor before using **Viscoflu®** because the presence of N-acetylcysteine may cause hypotension with dilation of the temporal artery and the possible occurrence of headache: pressure should be monitored in this case.
Viscoflu® should not be administered with anti-cough drugs because the reduction of the cough reflex may lead to the accumulation of bronchial secretions.
Viscoflu® can be administered together with bronchodilators, vasoconstrictors, etc., but should in this case be used for the shortest time possible.
It is not recommended to mix antibiotics with **Viscoflu®** solution. The N-acetylcysteine contained in **Viscoflu®** can interfere with the test for measuring salicylates and ketones in the urine.
You are recommended to inform your doctor or pharmacist before using **Viscoflu®** if you have recently taken any other drugs, including drugs obtained without prescription.

6. STORAGE CONDITIONS

It is recommended to open the **Viscoflu®** ampoule just before use. If the solution has been mixed with other drugs, it should be used in the shortest possible time and cannot be stored. The expiry date printed on the packaging refers to the uno-pened pack, correctly stored. Do not use **Viscoflu®** after the expiry date printed on the packaging. Keep it out of the reach and sight of children.

7. WARNING

When opening the ampoule **Viscoflu®** emits a sulphurous smell which does not affect the administration of the preparation in any way. The solution can sometimes turn a pink colour in the open ampoule or when drawn into the aerosol device, without compromising the activity and tolerability of the preparation. If you have any further questions on the use of **Viscoflu®** please contact your doctor or pharmacist. Patients with bronchial asthma must be closely monitored during therapy. If bronchospasm arises, the administration of N-acetylcysteine should be immediately suspended, and an appropriate treatment must be carried out.

8. DISPOSAL

When expired or requiring disposal, the device must be handled according to the regulations for waste management of the Local Competent Authority. The product or its packaging should not be released into the environment.

9. LEGEND

Ampoule:
l. = lot
sc. = shelf life
NAC = N-acetylcysteine
MD = medical device

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