

Viscoflu®

NASAL SPRAY

NaCl 3%

N-acetylcysteine 6%

Decongestant and fluidifier



30 ml bottle with activator spray
and protection cap

PRESERVATIVE FREE

1. IDENTIFICATION, COMPOSITION AND PURPOSE OF THE MD

1.1 DESCRIPTION AND INDICATIONS

Viscoflu® nasal spray is a medical device made from 3% hypertonic saline solution at controlled pH and 6% N-acetylcysteine. It is indicated to facilitate the fluidification and mechanical removal of mucus and/or muco-purulent secretions stagnant inside the nasal cavity (acute, subacute and slow-resolution rhinitis; chronic and muco-crusty rhinitis; vasomotor rhinitis) and inside the paranasal sinuses (acute and chronic sinusitis), improving the symptoms and course of acute, subacute and chronic inflammation of the upper respiratory tract.

1.2 CONTRAINDICATIONS AND LIMITATIONS OF USE

Hypersensitivity to the active ingredients or to any of the excipients. **Viscoflu®** nasal spray is contraindicated in children under 2 years of age. During pregnancy and breastfeeding **Viscoflu®** nasal spray should be administered only if absolutely necessary and under direct medical supervision.

1.3 COMPOSITION

One 30 ml bottle contains: N-acetylcysteine 1.8 g, sodium chloride 0.9 g. Excipients: sodium hydroxide, sodium edetate, purified water.

1.4 MECHANISM OF ACTION

Viscoflu® nasal spray acts by thinning dense and viscous mucus through the physical/mechanical action of its ingredients:

- buffered hypertonic sodium chloride solution: hypertonic saline solutions applied directly to respiratory mucosae draw water by osmosis. This increases the percentage of water in the mucus lining the epithelium, thinning it and thus facilitating its removal.
- N-acetylcysteine: acetylated amino acid cysteine variant, exerts a mucolytic action by direct contact with mucus. This action depends on presence in the molecule of sulphhydryl radicals, which are able to break the disulfide bonds of the mucoproteins conferring viscosity to mucus, by depolymerizing them.

2. PACKAGING FORMAT

Solution in a 30 ml glass bottle, with vertical activator spray and protection cap.

3. METHOD OF USE

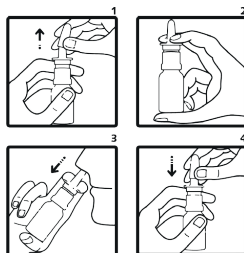
For correct use: remove the protection cap, tilt your head slightly backwards, gently place the activator into the opening of the nostril, press on the base of the activator using two fingers and spray 2-3 times in succession. Repeat the procedure in the other nostril. Clean the activator and replace the protection cap. Shake well before use.

3.1 DOSE, METHOD AND TIME OF ADMINISTRATION

The recommended dose is 2-3 sprays actuation in each nostril two to three times a day for no more than 10 days, depending on the clinical symptoms to be treated. This treatment can be repeated several times during the year, discontinuing the use of the product for at least 1 week between cycles. Use within 2 months of opening the bottle.

3.2 KNOWN SIDE EFFECTS

The high salt concentration of the solution can cause a natural burning sensation after spray activation; this effect disappears within a few minutes. Compliance with the leaflet instructions reduces the risk of side effects.



4. STORAGE CONDITIONS

Store at room temperature (not above 25°C) away from light and sources of heat. The expiry date refers to the product when unopened and correctly stored.

5. WARNINGS AND PRECAUTIONS

After spray actuation, **Viscoflu** nasal spray has a sulphureous odour which does not alter the preparation in any way. After each spray activation, wash the activator. It is recommended to replace the protection cap after use. Do not use in case of individual hypersensitivity or allergy to any of the ingredients of the product.

Prolonged use of topical products can lead to sensitisation effects; if these effects occur, discontinue treatment and consult your doctor. Keep the product out of the reach and sight of children. Do not use the medical device after the expiry date. Do not use if the packaging is damaged. Do not swallow. Do not spray into eyes. The use of the same bottle by more than one person can facilitate the transmission of infections.

6. DISPOSAL

When expired or requiring disposal, the device must be handled according to the waste management regulations of the relevant Local Authority. In any case, dispose of the product and its packaging responsibly.

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Keep out of the reach of children