Rinofluimucil

Nasal spray solution

1. NAME OF THE MEDICINAL PRODUCT
RINOFLUIMUCIL 1% + 0.5% nasal spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
100 ml contain:

Active ingredients

Acetylcysteine	g 1.000
Tuaminoheptane sulphate	g 0.500

As for excipients, see section 6.1

3. PHARMACEUTICAL FORM
Nasal spray, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
- Acute and subacute rhinitis, showing especially mucopurulent exudates with slow resolution.
- Chronic and mucous-crusty rhinitis.
- Vasomotor rhinitis.
- Sinusitis.

4.2 Posology and method of administration
RINOFLUIMUCIL is used for applications into the nasal cavities, by using the apposite metered-dose nebulizer (see section 6.6).
ADULTS: 2 nebulizations in each nostril 3-4 times a day.
CHILDREN over 12 years of age: 1 nebulization in each nostril 3-4 times a day.
Do not exceed the recommended doses.
Once opened, the bottle contents must be used within 20 days.

4.3 Contraindications
RINOFLUIMUCIL is contraindicated in patients with hypersensitivity to any of the product ingredients, in subjects with narrow-angle glaucoma and in case of hyperthyroidism. Do not administer during and in the two weeks following a therapy with monoamine oxidase inhibitors (MAOI). The drug is contraindicated in children below 12 years of age.

4.4 Special warnings and precautions for use
In patients suffering from cardiovascular diseases, and especially in hypertensive subjects, the use of nasal decongestants is to be submitted at any one time to the medical approval.
The product is to be administered with due caution in asthmatic patients. Special care is also required for the administration of Rinofluimucil in the paediatric age, being it however contraindicated in children below 12 years of age.
The prolonged use of preparations containing vasoconstrictors can alter the normal function of the nasal and paranasal sinuses mucosa, with the possible onset of drug addiction. Therefore repeated applications for long time periods can induce harmful effects.
The product is to be used with due caution in the elderly and in subjects suffering from prostatic hypertrophy, due to the risk of urinary retention.
The use, especially for long time periods, of topical products can lead to sensitization phenomena: in this case it is necessary to discontinue the treatment and, as the case may be, establish an adequate therapy. Anyway, in the absence of a complete therapeutic response within few days, consult the doctor; in any case the treatment duration must not exceed one week.
The action of the preparation can be supported, according to the doctor's opinion, by an appropriate antibacterial therapy.
The preparation is not suitable for ophthalmic use.
Keep away from the reach of children.

4.5 Interactions with other medicinal products and other forms of interaction
No particular medical interactions with the active ingredients contained in the medicinal specialty have been described in literature.

4.6 Pregnancy and lactation
In pregnant women the product must be used only in case of strict necessity and under direct medical control.

4.7 Effects on ability to drive and use machines
There are no assumptions or evidences that the drug can modify the attention capacity and the reaction times.

4.8 Undesirable effects
Frequent administrations of the preparation at the highest doses can induce side effects of sympathomimetic type (such as increase in excitability, palpitations, tremor, etc.). Sometimes nose and throat dryness and acneic eruptions may appear. Such effects disappear completely by treatment withdrawal.

4.9 Overdose
In case of overdose arterial hypertension, photophobia, intense headache, thoracic constriction may appear, and in children also hypothermia with marked sedation can be observed, requiring the adoption of adequate emergency measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamlc properties
Pharmacotherapeutic group: Rhinologic preparations - decongestants - associated sympathomimetics; **ATC code: ROIABO8**
The mucolytic and vasoconstrictive activities of the medicinal specialty reflect the pharmacological characteristics of the single ingredients.
Acetylcysteine is endowed with mucolytic activity, exerted through the breaking of disulfide linkages of mucoproteins by the free sulfhydryl, thus allowing the attainment of a fluidifying action on nasal-pharyngeal secretions.
Tuaminoheptane sulphate is a sympathomimetic amine exerting a vasoconstrictive action by topical use, without evident systemic effects.

5.2 Pharmacokinetic properties
The single ingredients of the medicinal specialty are not absorbed at active doses by systemic route.

5.3 Preclinical safety data
Studies performed to evidence possible local and/or systemic toxic effects demonstrated the good tolerability of the medicinal specialty on the mucous and serous surfaces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium chloride, Dithiothreitol, Sodium edetate, Dibasic sodium phosphate, Monobasic sodium phosphate, Sodium hydroxide, Alcohol, Hydroxypropylmethyl cellulose, Sorbitol 70%, Mint natural flavour, Depurated water q.s. to 100 ml.

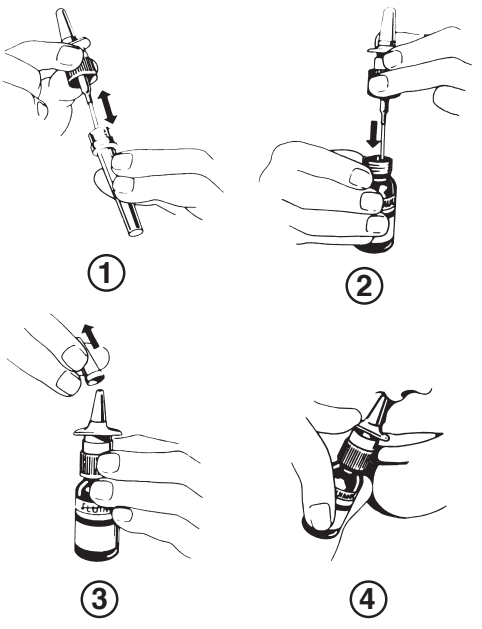
6.2 Incompatibilities
None known so far.

6.3 Shelf-life
30 (thirty) months.
The indicated expiry date refers to the product in its intact packaging and properly stored.
Once opened, the bottle contents must be used within 20 days.

6.4 Special precautions for storage
Store below 25 °C.

6.5 Nature and contents of container
Yellow glass bottle containing 10 ml of solution, closed with aluminium rubber ring with safety cover cap.
Box containing one 10 ml bottle, one screw nebulizing pump and the package leaflet.

6.6 Special precautions for disposal and other handling
Instructions for the bottle opening and the nebulizer use:
a) Open the bottle by tightening the ring sides and unscrewing concomitantly.
b) Screw the nebulizer after removing the stem protection.
c) Remove the nebulizer cap.
d) Press the pump many times to start it.



7. Manufacturer
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Zambon