Rinofluimucil 1% + 0.5% nasal spray solution

Pharmacotherapeutic category
Rinofluimucil is a fluidizing and nasal decongestant.

Therapeutic indications
Rinofluimucil is used for: Acute and subacute rhinitis with mucopurulent exudates and slow resolution. Chronic and mucus-crusted rhinitis. Vasomotor rhinitis. Sinusitis.

Contraindications
When it should not be used
• Hypersensitivity to the active substance or to any of the excipients.
• Narrow angle glaucoma.
• Hyperthyroidism.
• During and in the next two weeks therapy with antidepressant drugs (selective monoamine oxidase inhibitors).
• Children under the age of 12.
• Pheochromocytoma.
• During the use of other sympathomimetic agents, including other nasal decongestants.
• Hypophysectomy or surgery with exposure of the dura mater.

Precautions for use
When it can be used only after consulting your doctor
In children over 12 years, the product should be used only if clearly needed and under medical supervision. In patients with cardiovascular disease, especially in people with hypertension, the use of nasal decongestants should be from time to time subjected to the judgment of the physician. In patients with occlusive vascular disease, asthma, diabetes and treated with beta-blockers medication it should be used only after consulting your doctor. And advisable to consult your doctor, even in cases where such troubles have arisen in the past.
Precautions for use
In the elderly and in patients with prostatic hypertrophy, the product should be used with caution because of the risk of urinary retention. The action of the preparation can be integrated, in the opinion of the doctor, with an appropriate antibacterial coverage.

Interactions
Medications and food able to alter the effect of the medicine
Inform your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription. Despite the low systemic absorption of tuaminoheptane administered intranasally, they have to consider the following potential interactions:
• Monoamine oxidase inhibitors (MAOIs) including reversible inhibitors of monoamine oxidase (RIMA): increased risk of hypertensive crisis;
• Antihypertensive agents (including the adrenergic blockers and beta blockers neuron) can block the hypotensive effects;
• Cardiac glycosides may increase the risk of dysrhythmia;
• Ergot alkaloids: may increase the risk of ergotism;
• PD medications: can increase the risk of cardiovascular toxicity;
• Oxytocin: may increase the risk of hypertension.

Warnings
What to do during pregnancy and lactation
Pregnancy
Data from a limited number of pregnant women exposed to N-acetylcysteine did not indicate any adverse effect on the pregnancy or the fetus / newborn child. At present, there are no other relevant epidemiological data. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. There are no data on pregnant women exposed to tuoaminoheptane or studies on animals with tuoaminoheptane. Rinofluimucil is not recommended during pregnancy.

Nursing
There is no information available on the excretion of N-acetylcysteine and tuoaminoheptane into breast milk so it should not be used by nursing mothers.

It 'important to know that:
Prolonged use of preparations containing vasoconstrictors can alter the normal function of the lining of the nose and paranasal sinuses, causing even addiction to the drug. The repeat applications for long periods may be harmful.
The preparation is not for ophthalmic use.
Watch out for those who perform sporting activities: the product contains banned substances for doping. And 'forbidden intake different, dosing schedule and route of administration, from those reported.
For those who perform sporting activities, the use of medicines containing ethyl alcohol can cause positive doping tests in relation to the blood alcohol concentration limits indicated by some sports federations.
It contains the preservative benzalkonium chloride which may cause skin reactions and bronchospasm.

Effects on ability to drive and use machines
There are assumptions it 'evidence that the drug would affect attentional skills and reaction times.

Doses and Profiles
How to use this medicine
How much
Warning, do not exceed the prescribed dose unless recommended by your physician. Adults: 2 sprays in each nostril 3-4 times a day.
Children over 12 years: 1 spray in each nostril 3-4 times a day.
Rinofluimucil should be sprayed into the nasal cavity using a special dispenser.
When and for how long
Warning: Use only for short periods of treatment, but no later than one week. Consult your doctor if the disorder occurs repeatedly or if you have noticed any recent change in its characteristics.
As:
1. Open the bottle squeezing the sides of the capsule and unscrewing simultaneously.
2. Apply screw the pump spray, after releasing the float from protection.
3. Operate the pump several times to activate it.
overdose
If accidentally swallowed / taken an overdose of Rinofluimucil, tell your doctor immediately or go to the closest hospital.
In case of overdose may appear high blood pressure, photophobia, severe headache, chest tightness and hypothermia in children with strong sedation, which require the adoption of appropriate emergency measures.
IF YOU HAVE ANY DOUBTS ON THE USE OF Rinofluimucil, CONTACT YOUR DOCTOR OR PHARMACIST.

Side effects
Like all medicines, Rinofluimucil can cause side effects, although not everybody gets them.
The product may cause local sensitization and congestion of rebound mucosal.
frequent administration of the preparation at the higher doses can cause side effects such sympathomimetic (such as increased excitability, palpitations, tremor, etc.). Sometimes they may
experience dryness of the nose and throat and acne eruptions. These effects disappear with discontinuation of treatment.

The following side effects may be associated with using Rinofluimucil; the frequency of these side effects is not known (can not be made an estimate from the available data):

**System Organ Class Adverse Reactions**

**Immune system disorders**
- Hypersensitivity

**Psychiatric disorders, particularly with prolonged use and/or excessive anxiety, hallucination, delirium**

**Nervous system disorders**
- Particularly with prolonged use and/or excessive headache, restlessness, agitation, insomnia, tremor

**Heart disease**
- Particularly with prolonged use and/or excessive: palpitations, tachycardia, arrhythmia

**Vascular disorders**
- Hypertension

**Respiratory, thoracic and mediastinal disorders**
- Particularly with prolonged use and/or excessive: dry nose and throat, nasal discomfort, nasal congestion

**Gastrointestinal disorders**
- Nausea

**Skin and subcutaneous tissue**
- Hives, rashes

**Renal and urinary disorders**
- Urinary retention

**General disorders and administration site conditions**
- Irritability, addiction to medication

The respect of the information contained in the explanatory leaflet reduces the risk of side effects. These side effects are usually transient. When it is advisable for you to consult your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Ask for and fill in the report form undesirable effects form available at the pharmacy (B).

**Maturity and Conservation**

**Deadline:** See expiry date on the package.

**Caution:** Do not use the medicine after the expiration date on the package.

The expiry date refers to the sealed container when stored. Opened vials are used for a period not exceeding 20 days.

**KEEP THE MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN.**

It's important to always have available the product information, thus keep both the box and the package leaflet.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

**Composition and dosage form**

1 ml of solution contains:
- Active ingredients: N-acetylcysteine 10 mg, tuaminoheptane sulfate mg 5.
- Excipients: benzalkonium chloride, dithiothreitol, sodium edetate, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium hydroxide, alcohol, hypromellose, sorbitol, natural flavoring mint, purified water.

Rinofluimucil comes in the form of spray solution.