

PATIENT INFORMATION LEAFLET

Nasoxyl nasal spray solution 1 mg/ml

Read all of this leaflet carefully, because it contains important information for you.

This medicine is available without prescription. However, you still need to use **Nasoxyl** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

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1. What Nasoxyl is and what it is used for
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1. What Nasoxyl is and what it is used for

The active substance in Nasoxyl, xylometazoline, constricts the veins of the nasal mucosa and thus reduces mucous swelling due to different reasons and makes breathing through the nose easier. The effect begins quickly and lasts for 6 to 8 hours.

Nasoxyl is used for short-term treatment of nasal congestion with running nose in connection with common cold or sinusitis.

2. Before you use Nasoxyl

Do not use Nasoxyl:

- if you are hypersensitive to xylometazoline or any of the other ingredients in the product.
- if you have had recent brain surgery via the nose or mouth.

Take special care with Nasoxyl

Ask your doctor for advice before using the medicine if you have

- tendency towards hypersensitivity to sympathomimetics (adrenaline-like products); use may cause sleeplessness, vertigo, tremor, arrhythmia or elevated blood pressure.
- cardiovascular disease
- hypertension
- narrow chamber angle glaucoma
- hyperthyroidism (overactivity of the thyroid gland)
- diabetes
- pheochromocytoma (hormone-producing tumor in the core of an adrenal gland)
- prostatic hypertrophy (increase in size of the prostate gland).

Using other medicines

The product is not recommended to be used concomitantly with certain antidepressants, such as tri- or tetracyclic antidepressants or so-called MAO inhibitors (monoamine oxidase inhibitors) or for two weeks following the use of MAO inhibitors.

Tell your doctor if you are taking any medicines, including medicines obtained on prescription or without prescription, herbal products and natural products. Also inform the doctor of any medicines you have taken recently.

Pregnancy and breast-feeding:

The product should not be used during pregnancy. Discuss treatment during lactation with your doctor. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

When used correctly, the product does not have an effect on the ability to drive or use machines.

Important information about some of the ingredients of Nasoxyl

This medicine contains benzalkonium chloride as preservative, which can be irritant and may cause skin reactions or bronchospasm.

If used for a longer period, the preservative benzalkonium chloride may cause nasal mucosa swelling. In the case of such a reaction (persistently congested nose) medicinal products for nasal use without preservative should be used if possible. Unless such products are available another pharmaceutical form should be taken.

3. How to use Nasoxyl nasal spray solution 1 mg/ml

Always use exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For adults and children older than 6 years of age:

According to one's need 1 or more times, maximally 4-6 times a day, 1 spray in each nostril.

Nasoxyl is not recommended in children under 6 years. For children under 6 years other pharmaceutical form and strength are available.

Way of use

Nasal use

Blow the nose.

Remove the protective cover.

Before first use press the spray pump 5 times to prime. If you have not used the product for a maximum of 14 days (after first use), then first activate the spray pump by pressing the pump one time.

The nasal spray should be kept upright and the head should be bent forward lightly. Apply the opening of the nasal spray to the nostril and press the spray strongly. Pull the opening out of the nostril before removing the pressure. Apply one spray in each nostril. While pressing the spray, you should inhale through the nose. After use the opening of the spray should be cleaned and the protective cover should be put back.

Duration of the treatment

You may use Nasoxyl nasal spray solution 1 mg/ml for one week at most.

If the symptoms do not weaken or if they return within a week after you start using Nasoxyl nasal spray solution 1 mg/ml, you should consult your doctor.

Your doctor can advise you about the treatment of your disorder.

If you use more Nasoxyl nasal spray solution 1 mg/ml than you should:

If you take (or someone else takes) too large a dose of the medicine, contact your doctor without delay. Excessive doses may cause central nervous system depression, fatigue, dry mouth and sweating and symptoms caused by the stimulation of the sympathetic nervous systems (fast, irregular pulse and elevated blood pressure).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, Nasoxyl nasal spray solution 1 mg/ml can cause side effects, although not everybody gets them.

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

Common adverse effects of Xylometazolin HCL are a stinging or burning sensation in the nose and throat and dry nasal mucosa.

Rare adverse effects include headache, elevated blood pressure, nervousness, nausea, dizziness, sleeplessness and heart palpitation. Transient visual disturbances and systemic allergic reactions have also occurred.

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.

5. How to store Nasoxyl

Keep out of the reach and sight of children.

Do not use Nasoxyl after the expiry date which is stated on the carton and on the vial label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not freeze.

After opening any remaining solution should be discarded after 1 month.

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

6. Further information

What Nasoxyl contains

The active substance is xylometazoline hydrochloride.

1 ml nasal spray, solution contains 1 mg xylometazoline hydrochloride

1 single dose (140 microliter) contains 140 microgram xylometazoline hydrochloride.

The other ingredients are:

benzalkonium chloride

disodium edetate

sodium dihydrogen phosphate

disodium phosphate

sodium chloride

purified water

What Nasoxyl nasal spray solution 1 mg/ml looks like and contents of the pack

Nasoxyl nasal spray solution 1 mg/ml is a clear, colourless to nearly colourless solution.

Nasoxyl nasal spray solution 1 mg/ml is distributed in a brown, glass bottle (contents 10 ml) with a polyethylene dosing mechanism and a polypropylene cover.

Marketing Authorisation Holder

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