

Package leaflet: Information for the user

Nasoxyl Paediatric 0.05% nasal drops Xylometazoline HCl

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

1. What Nasoxyl Paediatric 0.05% nasal drops is and what it is used for
2. What you need to know before you use Nasoxyl Paediatric 0.05% nasal drops
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1. What Nasoxyl Paediatric 0.05% nasal drops is and what it is used for

Xylometazoline hydrochloride ensures fast and long lasting relief of nasal congestion, it reduces the swelling of mucous membranes in the nose. It thus helps to maintain a clear nasal passageway, making it easier to breathe if you suffer from a closed or congested nose.

The effect of this medicine starts within a few minutes and lasts for several hours. Xylometazoline is well tolerated even by patients with sensitive nasal mucosa.

Nasoxyl Paediatric 0.05% nasal drops is used for short-term treatment of nasal congestion due to inflammation of mucous membranes of the nose or sinuses with a congested or runny nose, sneezing and mucus (rhinitis or sinusitis) for infants and children up to 12 years of age.

You must contact a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you use Nasoxyl Paediatric 0.05% nasal drops

Do not use Nasoxyl Paediatric 0.05% nasal drops :

- if you are allergic to Xylometazoline hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if your child has recently undergone nasal surgery. Consult your doctor or pharmacist to see if you can start using xylometazoline hydrochloride.
- in infants and children up to 12 years of age.

Tell your doctor or pharmacist if these statements apply to your child, as it means this medicinal product is not suitable for your child.

Warnings and precautions

Talk to your doctor or pharmacist before using Nasoxyl Paediatric 0.05% nasal drops if your child suffers from one of the following conditions

- hypertension
- heart and cardiovascular diseases
- thyroid disease
- diabetes
- enlarged prostate
- tumor of the adrenal medulla (pheochromocytoma)
- narrow chamber angle glaucoma

If this is applicable to your child, talk to your doctor or pharmacist before administering this medicine.

As with other comparable medicinal products, Nasoxyl Paediatric 0.05% nasal drops can cause sleep disturbances, dizziness and tremor in people who are sensitive to this. Please contact your doctor if these kind of symptoms become annoying.

As with other products which reduce swelling of the nasal mucosa, you may not use Nasoxyl Paediatric 0.05% nasal drops continuously for more than a week at a time. Prolonged or excessive use can actually lead to thickening of the nasal mucosa, making it seem like the symptoms which you are using the nasal spray for did not disappear or even have returned.

If no improvement occurs within a week, contact your doctor.

Avoid contact with eyes and mouth.

The recommended dose should not be exceeded, especially in children and elderly.

Children

Other medicines and Nasoxyl Paediatric 0.05% nasal drops

Tell your doctor or pharmacist if you are using, have recently used or might start using any other medicines besides Nasoxyl Paediatric 0.05% nasal drops .

If you are using other medicines in combination with Nasoxyl Paediatric 0.05% nasal drops the following may occur:

- Increasing effect of Nasoxyl Paediatric 0.05% nasal drops when you use medicines against amongst others depressive moods (antidepressants)
- Changed effect of beta-blockers

Beta-blockers are medicines belonging to a certain group of drugs against high blood pressure, certain heart conditions and increased eye pressure

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Only use this medicine if your doctor has decided it can be used safely.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant. Use this medicine only if your doctor has decided that you can do this safely.

Breastfeeding

It is not known whether xylometazoline is excreted in human milk. A risk to the suckling child can not be excluded. One must decide to interrupt breastfeeding or to refrain from the xylometazoline therapy with consideration of the benefits of breastfeeding for the child and the benefit of therapy for you.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There is no data on the effect of this medicine on the ability to drive and use machines. However, it is unlikely that this medicine would have any effect.

Nasoxyl Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml contains benzalkonium chloride

The preservative of this medicinal product is benzalkonium chloride. This substance can be irritant and may cause skin reactions.

3. How to use Nasoxyl Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml

Always use this medicine exactly as described in this pack leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose:

For infants and children up to 6 years:

Under supervision of the parents

1-2 drops in each nostril, 1-3 times a day. There should be an interval of 8 to 10 hours between 2 administrations. Not more than 3 administrations per nostril per day.

Children aged 6 to 12 years:

Under supervision of the parents

2-4 drops in each nostril, 2-3 times a day. There should be an interval of 8 to 10 hours between 2 administrations. Not more than 3 administrations per nostril per day.

Use for a maximum of seven days in a row.

If used for more than seven days in a row, Nasoxyl Paediatric 0.05% nasal drops can cause nasal congestion.

Instructions for use

Blow the nose.

Before use, practice to obtain control over the dose.

Slightly bend the head backwards – making sure this remains comfortable – or, when lying on the bed, let the head hang over the edge of the bed.

Carefully apply the drops in each nostril without touching the nose. Hold the head backwards for a few moments, so that the fluid can disperse well all over the nose.

If drops did not go into the nose, administer them again.

If a small amount of the drops go into the nose, do not administer this drop again.

Repeat this procedure with the other nostril.

Clean and dry the pipet before putting it back in the bottle.

In order to avoid a possible spread of the infection, the vial should be used by 1 person only.

If you use more Nasoxyl Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml than you should

If your child used too much of the medicine, contact your doctor or pharmacist immediately.

If you forget to use Nasoxyl Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml

Do not take a double dose to make up for a forgotten dose.

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 Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml can cause side effects, although not everybody gets them.

Immediately STOP using this medicine and contact your doctor or go to the emergency department of a nearby hospital if you or your child shows any of the following symptoms, as these may be signs of an allergic reaction:

- difficulty in breathing and swallowing,
- swelling of the face, lips, tongue or throat,
- severe itching, accompanied by red rashes and hives (urticaria).

Common (affected less than 1 in 10 users):

- headache;
- dry nose or nasal discomfort, burning sensation;
- nausea.

Uncommon (affected less than 1 in 100 users):

- nose bleed.

Very rare (affected less than 1 in 10,000 users):

- dizziness;
- tremor;
- insomnia;
- disturbances of vision (visual disturbances), which are transient;
- irregular and rapid heartbeat,
- Increased blood pressure.

Data from clinical trials and post-marketing data suggests that xylometazoline is generally well tolerated in infants and children up to 6 years:. The frequency, type and severity of adverse reactions in children are expected to be similar in adults. The majority of adverse reactions reported in children occurred after overdose of xylometazoline.

If your child experiences hallucinations, restlessness or insomnia, stop taking this medicinal product.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help us provide more information on the safety of this medicine.

5. How to store Nasoxyl Paediatric 0.05% nasal drops

Keep out of the sight and reach of children.

Store below 25°C. Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle label after EXP. The expiry date refers to the last day of that month.

An opened package can be used up to 1 month after opening.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use in a responsible manner. These measures will help protect the environment.

6. Contents of the pack and other information

What Nasoxyl Paediatric 0.05% nasal drops contains

The active substance is xylometazoline hydrochloride.

1 ml nasal drops contains 0.5 mg xylometazoline hydrochloride

1 single dose (22 mg) contains 10.9 microgram xylometazoline hydrochloride.

The other ingredients are benzalkonium chloride, disodium edetate, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium chloride, purified water.

What Nasoxyl Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml looks like and contents of the pack

Nasoxyl Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml is a clear, colourless to nearly colourless solution.

NasoxyL Paediatric 0.05% nasal drops nasal drops 0.5 mg/ml is distributed in a brown, glass bottle (contents 10 ml) with a glass pipette with a thermoplastic bulb, a polypropylene cover and a polyethylene ring.

Marketing Authorisation Holder and Manufacturer

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