**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Nasadur 0,5 mg/ml neusspray, oplossing**

Xylometazoline hydrochloride

**Read all of this leaflet carefully before you start using this medicine because it contains important information for your child.**
This medicine is available without prescription. However, your child still needs to use Nasadur 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.
- If your child gets 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 your child does not feel better or if the child feels worse after 3 days.

**What is in this leaflet:**

1. What Nasadur is and what it is used for
2. What you need to know before you use Nasadur
3. How to use Nasadur
4. Possible side effects
5. How to store Nasadur
6. Contents of the pack and other Further information


## 1. WHAT NASADUR IS AND WHAT IT IS USED FOR

The active ingredient in this medicine is xylometazoline. It constricts blood vessels in the nasal mucosa, thereby reducing its swelling due to various causes, and makes breathing through the nose easier.

Nasadur is used for short-term treatment of nasal congestion in children between 2 and 10 years old.
You must talk to a doctor if your child does not feel better or if the child feels worse after 3 days.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE NASADUR

**Do not use Nasadur**
- if your child is allergic to xylometazoline or any of the other ingredients of this medicine (listed in section 6).
- if your child has had recent brain surgery through the nose or mouth.

- if your child has a dry inflammation of the nasal mucous membrane with formation of crusts (rhinitis sicca).

**Warnings and precautions**
Talk to your doctor or pharmacist before using Nasadur if your child has:
- a tendency to hypersensitivity to sympathomimetics (drugs, such as adrenaline); Nasadur may cause insomnia, dizziness, trembling, arrhythmia or increased blood pressure.
- cardiovascular disease (heart disease, e.g. long QT syndrome; high blood pressure)
- hyperthyroidism (overactive thyroid gland)
- diabetes mellitus
- phaeochromocytoma (tumour in the medulla of the adrenal glands that produces hormones)
- prostatic hypertrophy (enlarged prostate)
- inherited diseases caused by defective enzymes (porphyria)
- been receiving treatment with a drug for depression (MAO inhibitors)
- increased intra-ocular pressure (narrow angled glaucoma)

Mucous swelling (**swelling of the inner lining of the nose**) may recur in connection with stopping long-term treatment with xylometazoline. In order to prevent this, the **treatment period should be kept as short as possible.**
If you think that you have a bacterial infection, please consult with your doctor as an infection must be treated appropriately. This medicinal product should not be used by more than one person in order to prevent the risk of spreading infections.

If any of the above applies to your child, consult a doctor before using Nasadur.

**Other medicines and Nasadur**
Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.
It is not recommended to use this medicine together with certain antidepressants, such as:
- tri- or tetracyclic antidepressants
- MAO inhibitors (monoamine oxidase inhibitors) or if your child has taken MAO inhibitors within the last two weeks.

Also, it is not recommended to use this medicine:
- in combination with anti-hypertensive medicaments (e.g. methyldopa) due to the potential hypertensive effects of xylometazoline
- with other medicaments with potential hypertensive effect (e.g. doxapram, ergotamine, oxytocin) as they can potentiate each others hypertensive effects.

**Pregnancy and breast-feeding**
This strength of Nasadur is intended for use in children. Yet, this information applies to the active ingredient xylometazoline.
Pregnant or breast-feeding women should consult their doctor before using this medicine.

Pregnancy:

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Breast-feeding:
It is unknown whether xylometazoline is excreted in human milk. Risk to the breast-feeding child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from using Nasadur, taking into account the benefit of breast-feeding the child and the benefit of therapy for the mother.
As overdosing may lead to a reduction of milk production the recommended dose of xylometazoline must not be exceeded during breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
When taken properly, this medicine does not affect the ability to drive or operate machines, however if you feel drowsy or sleepy while using this medicine, you should not drive op operate machines.

## 3. HOW TO USE NASADUR

Before the first application it is necessary to spray a few times (4 times) in the air, to achieve a uniform dose. The bottle should be in a vertical position. If the product is not used for several days at least one test spray in the air should be done in order to achieve a uniform dose.

Nasadur 0.5 mg/ml is intended for the treatment of nasal congestion **in children between 2-10 years.**

**Dosage**
The usual dosage for children is one spray into each nostril, every 10-12 hours (no more than three times daily) **for a maximum of 5 days**.

Nasadur 0.5 mg/ml is **not recommended for children younger than 2 years**. The safety and efficacy of Nasadur 0.5 mg/ml in children younger than 2 years have not yet been established.

Patients older than 10 years should use Nasadur 1 mg/ml.

**Duration of treatment**
The duration of the therapy should be as short as possible. After long-term therapy, swollen mucosa (inner lining of the nose) may reappear. The recommended dose should not be exceeded.

**If the symptoms of your child's illness have not improved**
You must talk to a doctor if your child does not feel better or if the child feels worse after 3 days of continuous treatment.

The doctor may give you different dosage instructions than those provided in this patient information leaflet. Always use Nasadur exactly according to the instructions mentioned in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Instructions for use**

| | |
|---|---|
| The spray should be administered to the child while they are in an upright position. Therefore, it is best for small children to sit on your lap during the application.<br>Blow your child's nose before using this medicine. Remove the cap as shown in picture 1. | Picture 1<br> |
| Hold the bottle between your index and middle fingers while supporting the bottom with your thumb as shown in picture 2; To spray, press the pump in a downward direction.<br><br>When using this medicine for the first time, spray into the air a few times (4 times) in order to get fine mist. It is also good to test the pump before each use by pressing it down at least 1 time. | Picture 2<br> |
| Insert the pump into the nostril, as shown in picture 3. Press the pump downwards and at the same time have the child breathe in through the nose while you gently close the other nostril with the index finger of your other hand. Release the pump and remove from the nostril. Repeat this process in the other nostril.<br>Whip off the pump and replace the plastic cap after use. | Picture 3<br> |

Note: if the same spray bottle is used by several people, it may cause spread of the infection.

**If your child uses more Nasadur than he or she should**

If your child (or if someone else) has taken an overdose of this medicine, visit your doctor immediately. Overdose may cause a depression of the central nervous system, dry

mouth, sweating and symptoms caused by stimulation of the sympathetic nervous system (fast, irregular pulse and increased blood pressure).

**If you forget to use Nasadur**
If you forget to give a dose of this medicine skip the missed dose and carry on with the dosing schedule. Do not take a double dose to make up for a forgotten dose.

**If you stop using Nasadur**
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

*Common: may affect up to 1 in 10 people*
- itching or burning in the nose and throat
- dry nasal mucosa.

*Uncommon: may affect up to 1 in 100 people*
- hypersensitivity reactions (swelling of skin and mucous membranes, skin rash, itching)
- increased swelling of the nasal mucosa after discontinuation of treatment
- epistaxis (nose bleeding)

*Rare: may affect up to 1 in 1,000 people*
- heart palpitations and tachycardia (rapid heart rate)
- nausea
- high blood pressure.

*Very rare: may affect up to 1 in 10,000 people*
- nervousness
- insomnia
- fatigue
- headache
- arrhythmia
- mainly in children and after overdosing: sleepiness/drowsiness, nervousness, insomnia, hallucinations and convulsions. Cases of irregular breathing have been recorded in infants and neonates.

**Reporting of side effects**
If your child gets 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

Nederlands Bijwerkingen Centrum Lareb, website: www.lareb.nl
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE NASADUR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'Exp'. The expiry date refers to the last day of the month.
Use within 3 months after opening.

Do not freeze. This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Nasadur contains**
- The active substance is xylometazoline hydrochloride, whereby 1 millilitre of the solution contains 0.5 mg. 1 spray of Nasadur 0.5 mg/ml (= 90 microlitres) contains 45 micrograms of xylometazoline hydrochloride.
- Other ingredients are purified sea water, potassium dihydrogen phosphate, and purified water.

**What Nasadur looks like and contents of the pack**
Nasadur is a clear, colourless solution.
Each package contains one bottle filled with 10 ml of this solution.

**Marketing authorization holder and manufacturer**

Marketing authorization holder
JADRAN-GALENSKI LABORATORIJ d.d.
Svilno 20
51000 Rijeka
Croatia

Manufacturer
JADRAN-GALENSKI LABORATORIJ d.d.
Svilno 20
51000 Rijeka
Croatia

**In het register ingeschreven onder:** RVG 107408

**This medicinal product is authorised in the Member States of the EEA under the following names:**

| | |
|---|---|
| The Netherlands | Nasadur 0,5 mg/ml neusspray, oplossing |
| Germany | Imidin für Kinder o.K. 0.05% |

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2019**