

Package leaflet: Information for the user

<INVENTED NAME> 0.5 mg/ml nasal spray, solution *xylometazoline hydrochloride*

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

Always take 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 3 days.

What is in this leaflet

1. What <Invented name> 0.5 mg/ml is and what it is used for
2. What you need to know before you use <Invented name> 0.5 mg/ml
3. How to use <Invented name> 0.5 mg/ml
4. Possible side effects
5. How to store <Invented name> 0.5 mg/ml
6. Contents of the pack and other information

1. What <Invented name> 0.5 mg/ml is and what it is used for

<Invented name> 0.5 mg/ml contains xylometazoline, which helps to narrow the blood vessels in your nose, reducing swelling of the mucous membrane (the lining in your nose) to help you breathe easier.

The spray is used for short-term treatment of nasal or sinus congestion with a runny nose due to common cold or sinusitis.

2. What you need to know before you use <Invented name> 0.5 mg/ml

Do NOT use <Invented name> 0.5 mg/ml if you or your child:

- are allergic to xylometazoline or any of the other ingredients of this medicine (listed in Section 6),
- have increased pressure in your eye, especially if you have narrow angle glaucoma,
- have chronic rhinitis (long term nasal irritation) with little or no secretion (rhinitis sicca),
- are being treated with monoamine oxidase inhibitors (MAOIs) or if you have used MAOIs within the previous 2 weeks,
- are being treated with other medicines that could raise your blood pressure,
- have inflammation caused by the blood vessels in your nose being over-sensitive,
- have inflammation associated with thinning of the nasal membranes with or without discharge, - have had recent brain surgery via the nose or mouth.

This spray is not for use in children under 2 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using the spray if you or your child:

- react strongly to sympathomimetics (adrenaline-like products) as the use of <Invented name> 0.5 mg/ml may cause sleeplessness, dizziness, uncontrollable trembling or shaking movements, irregular heartbeat or abnormal heart rhythm, or an increase in blood pressure,
- have a heart problem, suffer from a heart disease (e.g. long QT syndrome), blood vessel problem or high blood pressure,
- have an overactive thyroid gland, diabetes or other any metabolic disorders,
- have a disease of your adrenal glands,
- have an enlarged prostate gland (prostatic hypertrophy).

Continuous use of the spray over long periods can result in worsening of inflammation of the sinuses or lining in your nose.

Other medicines and <Invented name> 0.5 mg/ml

Talk to your doctor or pharmacist before using <Invented name> 0.5 mg/ml.

Do not use the spray if you or your child is taking:

- certain antidepressants, such as tri- or tetracyclic antidepressants or MAOIs or if you have taken MAOIs in the last 2 weeks (see section 'Do not use')
- other medicines that could raise your blood pressure.

Please tell your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant or think you might be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. <Invented name> 0.5 mg/ml should not be used during pregnancy as little is known about its action on the unborn child.

If you are breast-feeding, discuss with your doctor before using this product. It is not known whether the active substance is transferred into breast milk.

Driving and using machines

<Invented name> 0.5 mg/ml has no known effects on the ability to drive or use machines.

<Invented name> 0,5 mg/ml contains benzalkonium chloride

This medicine contains 0.2 mg benzalkonium chloride in each ml which is equivalent to 0.014 mg/0.070 ml spray. Benzalkonium chloride may cause irritation or swelling inside the nose especially if used for a long time.

3. How to use <Invented name> 0.5 mg/ml

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

Children aged 2-12 years

Unless otherwise directed by a doctor or pharmacist, use one spray of <Invented name> 0.5 mg/ml in each nostril up to 3 times a day **for a maximum of 7 days**. Don't exceed recommended dose.

1. Take off the protective cap. Prime the bottle before using by pushing several times until the spray comes out in a steady squirt (see Figure 1). The spray is now ready to use.
2. Hold the bottle upright. Insert the nozzle into your nostril - do not spray from below the nostril (see Figure 2).
3. Press the pump once. At the same time, breathe in through the nose. Repeat for the other nostril.
4. After use, put the protective cap back on the bottle.



To reduce the risk of spreading infections, the bottle should not be used by more than one person, and the nozzle should be rinsed after each use.

Do not use this spray in children under 2 years.

If you use more <Invented name> 0.5 mg/ml than you should

Contact your doctor, pharmacist or nearest hospital casualty department immediately, and take the medicine or this leaflet with you.

Excessive doses may result in the paralysis of the central nervous system e.g. loss of muscle function, tiredness, dry mouth, sweating, fast, irregular pulse and raised blood pressure.

If you forget to use <Invented name> 0.5 mg/ml

If you forget to take a dose, take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

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

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

4. Possible side effects

Like all medicines, <Invented name> 0.5 mg/ml can cause side effects, although not everybody gets them.

STOP using the spray and seek medical help immediately if you or your child has any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Other side effects may include:

Common (may affect up to 1 in 10 people):

- stinging or burning sensation in the nose and throat and dry lining of the nose (nasal mucosa).

Rare (may affect up to 1 in 1,000 people):

- headache, raised blood pressure, nervousness, feeling sick, dizziness, sleeplessness and heart palpitations.
- temporary visual disturbances and systemic allergic reactions

Not known (frequency cannot be estimated from the available data):

- worsening of inflammation of the sinuses or lining in your nose after stopping use of the product.
- nose bleeding.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name> 0.5 mg/ml

Keep out of the sight and reach of children.

Store below 30°C.

After opening, do not use <Invented name> 0.5 mg/ml for more than 20 weeks.

Do not use <Invented name> 0.5 mg/ml after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 <Invented name> 0.5 mg/ml contains

The active substance is xylometazoline hydrochloride, of which there is 0.5 mg per millilitre of solution. Each actuation (spray release) (=0.070 ml) of <Invented name> 0.5 mg/ml contains 35 µg (or 0.035 mg) of xylometazoline hydrochloride.

The other ingredients are: disodium edetate, sodium chloride, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sorbitol (E420), benzalkonium chloride solution and purified water.

What <Invented name> 0.5 mg/ml looks like and contents of the pack

The spray is a clear, colourless solution in a 10 ml brown glass bottle with a dosage pump.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

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

Latvia: Olynth 0,5 mg/ml deguna aerosols, šķīdums

Romania: Olynth 0,5 mg/ml spray nazal, solutie

This leaflet was last revised in: MM/YYYY