

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zymelin, 0,5 mg/ml and 1 mg/ml nasal spray, solution

Xylometazoline hydrochloride

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 <Invented Name> 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 after 5 days (0,5 mg/ml) or 10 days (1 mg/ml).
- 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.

In this leaflet:

1. What <Invented Name> is and what it is used for
2. Before you use <Invented Name>
3. How to use <Invented Name>
4. Possible side effects
5. How to store <Invented Name>
6. Further information

1. WHAT <INVENTED NAME> IS AND WHAT IT IS USED FOR

<Invented Name> is used for symptomatic relief of nasal congestion caused by rhinitis or sinusitis.

<Invented Name> contains xylometazoline hydrochloride, which makes the blood vessels in the nose contract, thus enables you to breathe easier through the nose.

2. BEFORE YOU USE <INVENTED NAME>

Do not use <Invented Name>

- if you are allergic (hypersensitive) to xylometazoline hydrochloride or any of the other ingredients of <Invented Name>.
- if you have had the hypophysis removed by operation through the nose.
- after operations through the nose or mouth, where the membrane of the brain may have been exposed and/or damaged.
- if you suffer from glaucoma (increased pressure in the eye).

Take special care with <Invented Name>

- if you are sensitive to adrenergic substances that can give symptoms such as insomnia, dizziness, tremor, cardiac arrhythmia or high blood pressure.
- if you suffer from cardiovascular disease (e.g. long QT syndrome) or elevated blood pressure.
- if you suffer from diabetes mellitus.
- if you suffer from increased release of thyroid gland hormone (hyperthyroidism).
- if you are having problems with urination due to enlarged prostate.
- if you are treated with medicine for depression (Tri-cyclic or tetra-cyclic antidepressive or MAO inhibitors).
- if you have a benign growth which produce a large amount of adrenaline or noradrenaline (pheochromocytoma).

<Invented Name> 0,5 mg/ml and 1 mg/ml nasal spray should not be given to children under the age of 2 because of risk of overdosing followed by depression of the central nervous system.

The duration of treatment (0,5 mg/ml: max. 5 days, 1 mg/ml: max. 10 days) should not exceed the recommended time as long term or frequent treatment may lead to dependence and rebound congestions with chronic rhinitis, nasal hyperreactivity, tolerance, and histological changes of the nasal mucosa.

Using other medicines

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

If <Invented Name> is used concomitantly with tri-cyclic or tetra-cyclic antidepressives (such as amitriptyline, nortriptyline, imipramine, clomipramine and trimipraine) or MAO-inhibitors (such as isocarboxazid and moclobemid) the possibility for systemic side effects (i.e. nausea, vomiting and headache) can increase.

Using <Invented Name> with food and drink

<Invented Name> can be used independently of intake of beverages and food.

Pregnancy and breast-feeding

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

<Invented Name> should not be used if you are pregnant. Pregnant women are advised to see a physician before use.

<Invented Name> can be used with caution during lactation.

Driving and using machines

<Invented Name> has no influence on the ability to drive or use machines.

3. HOW TO USE <INVENTED NAME>

Always use <Invented Name> exactly as described in this leaflet, unless you have been given other instructions by a doctor. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Nasal spray 1 mg/ml, adults and children over the age of 10 years:

1 puff in each nostril maximum 3 times daily.

The treatment may continue until the symptoms are gone, however maximum duration of treatment is 10 days.

<Invented Name> 1 mg/ml should not be given to children under the age of 10 without a doctor's recommendation.

<Invented Name> 1 mg/ml should not be given to children under the age of 2.

Nasal spray 0,5 mg/ml, children 2-10 years:

1 puff in each nostril maximum 3 times daily.

The treatment may continue until the symptoms are gone, however maximum duration of treatment is 5 days.

<Invented Name> 0,5 mg/ml should not be given to children under the age of 2.

Use <Invented Name> in the following way: Always blow your nose before using the nasal spray.

Remove the dust cap.

Before using the pump for the first time: Pump the spray a number of times until a uniform spray is obtained.

- Hold the bottle upright.
- Bend your head slightly forward.
- Close one nostril by placing your finger against the side of your nose and insert the spray tip into the other nostril. Press the pump quickly while inhaling through the nose. - Repeat this procedure in the other nostril.

The effect begins within 5-10 minutes after application and lasts for up to 6-8 hours.

If you use more <Invented Name> than you should

If you have taken more medicine than you should, contact your doctor, hospital or emergency room for assessment of the risk and for advice.

Symptoms of overdose (particularly in children) are increased or irregular pulse, increased blood pressure and, in some cases, unconsciousness.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, <Invented Name> can cause side effects, although not everybody gets them.

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.

Common side effects (occur in more than 1 of 100 users): Stinging in the nose and throat, dry and irritated nasal mucous membrane, sneezing, temporarily burning sensation in the nose, nasal secretion.

Uncommon side effects (occur in less than 1 of 100 users): blockage of the nose (reactive hyperaemia), especially after frequent or prolonged use, Nosebleeds.

Rare side effects (occur in less than 1 of 1000 users): Nausea, vomiting.

Very rare side effects (occur in less than 1 of 10,000 users): Severe allergic reactions, tachycardia or irregular pulse, restlessness, insomnia, tiredness, headache, temporarily disturbed vision.

5. HOW TO STORE <INVENTED NAME>

Keep out of the reach and sight of children.

Do not use <Invented Name> after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30 °C.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What <Invented Name> contains

- The active substance is xylometazoline hydrochloride.
0,5 mg/ml: 1 ml contains 0,5 mg xylometazoline hydrochloride and 1 puff contains 35 micrograms xylometazoline hydrochloride.
1 mg/ml: 1 ml contains 1 mg xylometazoline hydrochloride and 1 puff contains 140 micrograms xylometazoline hydrochloride.
 - The other ingredients are disodium edetate, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium chloride and water, purified.
- <Invented Name> is preservative free.

What <Invented Name> looks like and contents of the pack

<Invented Name> is a clear, colourless solution. <Invented Name> is available as:

- 0,5 mg/ml: a 10 ml nasal spray with pump.
- 1 mg/ml: a 10 ml nasal spray with pump. Not all pack sizes may be marketed.

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:

Denmark: Xylometazolin ukonserveret Orifarm

Sweden: Zymelin

This leaflet was last approved in 21 May 2025.