

Package leaflet: Information for the user

Xylometazoline Decongestant Nasal Spray 0.1%w/v

Xylometazoline hydrochloride 0.1% w/v

Read all of this leaflet carefully before you start taking 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 the nasal spray is and what it is used for
2. What you need to know before you use the nasal spray
3. How to use the nasal spray
4. Possible side effects
5. How to store the nasal spray
6. Contents of the pack and other information

1. WHAT THE NASAL SPRAY IS AND WHAT IT IS USED FOR

Xylometazoline Decongestant Nasal Spray (hereinafter referred to as nasal spray) contains a nasal decongestant. Nasal decongestants help clear blocked noses associated with a number of conditions including colds, sinusitis, and hay fever.

A blocked nose, such as occurs with a cold, is caused by excessive nasal secretions and the swelling up of many tiny blood vessels that line the nose. The air passages become narrower and the nasal secretions may block the nose completely.

The nasal decongestant in this product helps to open up the nasal passages by reducing the excessive nasal secretions and reducing the swollen blood vessels to their normal size. It will help you breathe more easily and so feel better.

You must talk to 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 THE NASAL SPRAY

Do not use the nasal spray if you:

- are allergic to xylometazoline hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have had recent neurosurgery
- have narrow angle glaucoma
- have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis)
- have an enlarged prostate gland
- have a rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma)

- are taking monoamine oxidase inhibitors (MAOIs) or have stopped taking them in the last 14 days

Do not use this spray for children under 12 years old.

Warnings and precautions

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

- have an overactive thyroid gland (hyperthyroidism)
- have diabetes mellitus
- have heart or circulatory disease (e.g. long QT syndrome)
- are pregnant or breast-feeding
- have hypertension

Like other products for the relief of blocked nose, the nasal spray may give rise to sleep disturbances, dizziness, tremor in very sensitive patients. Consult your doctor if such signs prove troublesome.

Do not take decongestants for more than 7 days in a row. Prolonged or excessive use may cause stuffiness to return or worsen.

Other medicines and the nasal spray

Tell your doctor or pharmacist if you are taking or using, have recently taken or used or might take or use any other medicines, (especially monoamine oxidase inhibitors or other antidepressants) including medicines obtained without a prescription.

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 using this medicine.

Driving and using machines.

This medicine has no effect on the ability to drive and use machines.

Xylometazoline Decongestant Nasal Spray contains benzalkonium chloride and sodium

This medicine contains 1.5mg benzalkonium chloride in each 10ml which is equivalent to 1.5mg/10ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. HOW TO USE THE NASAL SPRAY

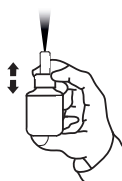
For adults and children over 12 years of age:

One spray in each nostril up to 3 times daily. Do not exceed 3 applications daily into each nostril.

1. Clear the nose.
2. Remove the protective cap.

(continued overleaf)

3. If you use the bottle for the first time, you should first press the pump 5 times until an even spray is formed. The next time you use the bottle this will no longer be necessary. If you have not used the bottle for 14 days maximum (after first use), press the pump 1 time to prepare the bottle for use again. Make sure not to spray into the eyes or mouth.



4. Keep the bottle upright between thumb and fingers.
5. Keep the nozzle upright properly, tilt your head forward slightly and place the nozzle in a nostril.
6. Spray once in each nostril. Breathe through your nose whilst pressing down the pump.
7. Clean and dry the nozzle before replacing the dust cap.



Not recommended for use in children under 12 years of age.

To avoid the possible spread of infection, these drops should be used by one person only.

If you use more nasal spray than you should

Consult your doctor if you think that you have used too much solution or have taken it accidentally by mouth.

If you forgot to use the nasal spray

If you forget to use the nasal spray, use as soon as you remember. If it is almost time for your next dose, wait until that is due and then continue as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on this 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.

Stop using this medicine and **seek medical help immediately** if you experience:

- Allergic reactions, which may include difficulty breathing or swallowing, swelling of the face, lips, tongue and throat, severe itching of the skin, with a red rash or raised bumps.

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

- Headache
- Nasal dryness
- Nasal discomfort
- Nausea
- Local irritation after using the spray

Uncommon (may affect up to 1 in 100 people):

- Nosebleeds

Very rare (may affect up to 1 in 10,000 people):

- Hypersensitivity including rash and pruritus
- Disturbances of vision
- Palpitations and increased heart rate

Other side effects include:

- A burning sensation in the nose and throat

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THE NASAL SPRAY

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 bottle. The expiry date refers to the last day of that month.

Store below 25°C. Do not freeze.

For reasons of hygiene do not use the spray for more than 28 days after first opening the bottle.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What the nasal spray contains

The nasal spray contains xylometazoline hydrochloride 0.1%w/v as the active ingredient. They also contain benzalkonium chloride, disodium edetate dihydrate, sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium chloride and purified water.

What the nasal spray looks like and contents of the pack

The nasal spray is a clear and colourless solution available in a 10ml bottle.

MA Holder:

Manx Healthcare Ltd
Unit 2, Bosworth Avenue, Tournament Fields,
Warwick, CV34 6UQ, UK

Manufacturer:

Basic Pharma Manufacturing BV
Burgemeester Lemmensstraat 352, 6163 JT
Geleen,
The Netherlands

Other formats

To request a copy of this leaflet in Braille, large print or audio, please call 01926 482511.

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