

**Package leaflet: Information for the user****Xylozolin 0,5 mg/ml, neusspray, oplossing**

Xylometazoline hydrochloride 0.5 mg/ml

**Xylozolin 1 mg/ml, neusspray, oplossing**

Xylometazoline hydrochloride 1 mg/ml

**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 have 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 {(Invented) name strength pharmaceutical form} is and what it is used for
2. What you need to know before you use {(Invented) name strength pharmaceutical form}
3. How to use {(Invented) name strength pharmaceutical form}
4. Possible side effects
5. How to store {(Invented) name strength pharmaceutical form}
6. Contents of the pack and other information

**1. What {(Invented) name strength pharmaceutical form} is and what it is used for**

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

{(Invented) name strength pharmaceutical form} contains the active ingredient xylometazoline, which is a topical decongestant that relieves nasal congestion. A decongestant reduces the swelling of the nasal mucosa.

{(Invented) name strength pharmaceutical form} is used for temporary symptomatic treatment of nasal congestion due to rhinitis or sinusitis.

**{(Invented) name 0.5 mg/ml pharmaceutical form} is intended for children between 2 and 10 years of age.**

**{(Invented) name 1 mg/ml pharmaceutical form} is intended for adults as well as for children 10 years of age and older.**

**2. What you need to know before you use {(Invented) name strength pharmaceutical form}****Do NOT use {(Invented) name strength pharmaceutical form}**

- if you are allergic to xylometazoline or any of the other ingredients of this medicine (listed in section 6).
- if you have recently had neurosurgery (transspenoidal hypophysectomy or other surgery exposing the meninx)
- if you suffer from dry rhinitis (a form of chronic rhinitis that causes dry inflammation of the nasal mucous membrane with formation of crusts).

**{(Invented) name 0.5 mg/ml pharmaceutical form}**

- in children younger than 2 years of age.

**{(Invented) name 1 mg/ml pharmaceutical form}**

- in children below 10 years of age.

**Warnings and precautions**

Talk to your doctor or pharmacist before using {(Invented) name strength pharmaceutical form}

- if you are being treated with certain drugs for depression known as monoamine oxidase inhibitors (MAO inhibitors) or other medicinal products that may increase blood pressure.
- if you suffer from a heart disease (e.g. long QT syndrome), coronary heart disease or high blood pressure.
- if you suffer from an adrenal tumor (phaeochromocytoma).
- if you suffer from metabolic disorders such as thyroid hyperfunction (hyperthyroidism), or diabetes
- if you have an enlarged prostate.
- if you suffer from porphyria (a metabolic disorder that affects the skin and/or nervous system).
- if you suffer from increased pressure inside the eye, particularly narrow-angle glaucoma. Direct contact with the eyes should be avoided.

Long-term use of Xylometazoline nasal spray (longer than 7 days) may lead to chronic swelling and ultimately to the wasting away of the nasal mucous membrane (tissue inside the nose).

### Children

**{(Invented) name 0.5 mg/ml pharmaceutical form}**

{(Invented) name 0.5 mg/ml pharmaceutical form} must not be used in infants, toddlers and children below 2 years of age.

**{(Invented) name 1 mg/ml pharmaceutical form}**

{(Invented) name 1 mg/ml pharmaceutical form} must not be used by children younger than 10 years of age.

### Other medicines and {(Invented) name strength pharmaceutical form}

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Combined use of {(Invented) name strength pharmaceutical form} and certain drugs for depression (MAO inhibitors of the tranylcypromine type or tricyclic antidepressants) as well as high blood pressure (hypertension) medications can lead to a rise in blood pressure.

### Pregnancy, breast-feeding and fertility

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.

Since the safety of use of {(Invented) name strength pharmaceutical form} during pregnancy and breast-feeding has not been sufficiently documented, you may use {(Invented) name strength pharmaceutical form} only upon the recommendation of your doctor and only after a careful risk-benefit evaluation. As overdosing may affect the blood supply to the unborn child or lead to a reduction of milk production, the recommended dose must not be exceeded during pregnancy and breast-feeding.

### Driving and using machines

This medicine should not affect your ability to drive or operate machinery.

### 3. How to use {(Invented) name strength pharmaceutical form}

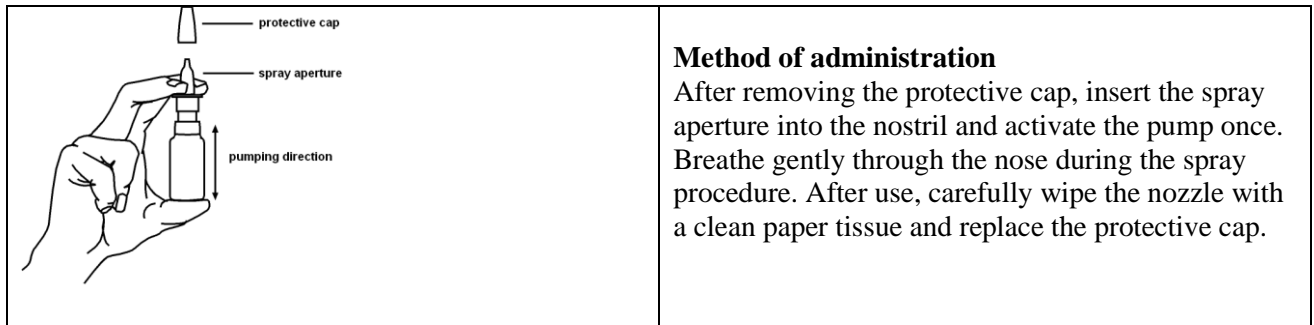
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**{(Invented) name 0.5 mg/ml pharmaceutical form}**

Unless otherwise prescribed by your doctor, the usual dose in children between 2 and 10 years of age is one spray of {(Invented) name 0.5 mg/ml pharmaceutical form} into each nostril, according to need, but up to a **maximum** of 3 times daily.

**{(Invented) name 1 mg/ml pharmaceutical form}**

Unless otherwise prescribed by your doctor, the usual dose in adults and children 10 years of age and older is 1-2 sprays of {(Invented) name 1 mg/ml pharmaceutical form} into each nostril, according to need, but up to a **maximum** of 3 times daily.



**Notes:**

Before the first use - and after interruption of treatment of more than 15 days - activate the pump several times until an even spray mist emerges. For subsequent applications, the metered-dose spray is ready for immediate use.

Before application of the nasal spray gently blow your nose. It is recommended to take the last dose of each day before you go to bed.

For hygienic reasons and to avoid infections, each spray bottle should only be used by the same person.

**Duration of use**

{(Invented) name strength pharmaceutical form} must not be used for longer than 7 days, unless prescribed by your doctor.

An interval of several days should elapse before re-administering the product.

When used to treat chronic rhinitis, the nasal spray may only be administered under medical observation, due to the risk of nasal mucosal atrophy (the wasting away of the skin inside the nose).

If you think the effect of {(Invented) name strength pharmaceutical form} is too weak or too strong, talk to your doctor or pharmacist.

**If you use more {(Invented) name strength pharmaceutical form} than you should**

In cases of significant overdose or accidental intake, in both children and adults, you must tell your doctor immediately. Monitoring and treatment in a hospital are necessary.

The following effects can occur:

- dilated or constricted pupils
- feeling sick (nausea) and vomiting
- pallor, blue colouration of skin and lips
- fever, sweating or also fall in body temperature
- heart circulation problems, such as a heartbeat that is too slow, too fast, or irregular, rise or fall in blood pressure
- suspension of breathing (apnoea)
- lethargy, drowsiness and coma
- anxiety, excitation, hallucinations and fits (convulsions).

Particularly in children, overdose can frequently be followed by convulsions and coma, slow heart rate, suspension of breathing (apnoea) and a rise in blood pressure, which can be followed by a fall in blood pressure.

**If you forget to use {(Invented) name strength pharmaceutical form}**

Do not take a double dose to make up for a forgotten dose, but continue to use as described in the dosage instructions.

If you have any further questions on the use of this product, 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 frequency conventions are used in the evaluation of side effects:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

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

Not known: frequency cannot be estimated from the available data

##### **Common**

- slight temporary irritation symptoms such as stinging or dryness of the nasal mucosa (tissue inside the nose) and/or throat.
- sneezing

##### **Uncommon**

- hypersensitivity reactions (skin rash, itching, swelling of skin and mucous membranes)
- after the effect has subsided increased sensation of a “blocked” nose
- nosebleed

##### **Rare**

- increased heart rate
- increase in blood pressure
- feeling your heart beat (palpitations)
- feeling sick (nausea)

##### **Very rare**

- nervousness (restlessness)
- difficulty falling or staying asleep (insomnia)
- sleepiness/drowsiness (mainly in children)
- headache
- dizziness
- hallucinations or fits (mainly in children)
- irregular heart beat
- stop breathing (apnoea) in infants and neonates

##### **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 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 strength pharmaceutical form}**

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

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

This medicinal product does not require any special storage conditions.

After first opening, {(Invented) name strength pharmaceutical form} should be used within 1 year.

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 {(Invented) name strength pharmaceutical form} contains

- The active substance is xylometazoline hydrochloride.  
**{(Invented) name 0.5 mg/ml pharmaceutical form}**  
One spray (equivalent to 0.09 ml solution) contains 0.045 mg xylometazoline hydrochloride.  
**{(Invented) name 1 mg/ml pharmaceutical form}**  
One spray (equivalent to 0.09 ml solution) contains 0.09 mg xylometazoline hydrochloride.
- The other ingredients are: citric acid monohydrate, sodium citrate dihydrate, glycerol 85%, water for injections.

### What {(Invented) name strength pharmaceutical form} looks like and contents of the pack

{(Invented) name **0.5 mg/ml** pharmaceutical form} is a clear, almost colourless solution available in a brown glass bottle containing 10 ml (not less than 90 actuations) or 2x10 ml (not less than 2x90 actuations) of solution sealed with a spray pump with a nose adapter and a protecting cap.

**{(Invented) name 1 mg/ml pharmaceutical form}** is a clear, almost colourless solution available in a brown glass bottle containing 10 ml (not less than 81 actuations), 15 ml (not less than 126 actuations) or 2x10 ml (not less than 2x81 actuations) of solution sealed with a spray pump with a nose adapter and a protecting cap.

< *Not all pack sizes may be marketed* >

### Houder van de vergunning voor het in de handel brengen en fabrikant

*Houder van de vergunning voor het in de handel brengen*

Pharmachemie B.V.  
Swensweg 5  
2031 GA Haarlem  
Nederland

*Fabrikant*

Merckle GmbH  
Ludwig-Merckle-Straße 3  
89143 Blaubeuren  
Duitsland

Pharmachemie B.V.  
Swensweg 5  
2031 GA Haarlem  
Nederland

Teva Czech Industries s.r.o.  
Ostravska 29, c.p. 305  
74770 Opava-Komarov  
Tsjechië

Teva Operations Poland Sp. Z o.o.  
Ul. Mogilska 80  
31-546 Krakow  
Polen

**In het register ingeschreven onder**

RVG 109042 - Xylozolin 0,5 mg/ml, neusspray, oplossing

RVG 109043 - Xylozolin 1 mg/ml, neusspray, oplossing

**Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

Denemarken	Xylometazolin Teva
Nederland	Xylozolin 0,5 mg/ml, neusspray, oplossing
	Xylozolin 1 mg/ml, neusspray, oplossing

Deze bijsluiter is voor het laatst goedgekeurd in juni 2023