

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Zymelin 0.5 mg/ml nasal spray, solution

Zymelin 1 mg/ml nasal spray, solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Xylometazoline hydrochloride 0.5 mg/ml and 1 mg/ml

(1 dose contains about 35 micrograms and about 140 micrograms respectively.)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, solution.

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of nasal congestion caused by rhinitis and sinusitis.

4.2 Posology and method of administration

Adults and children over the age of 10 years:

Nasal spray 1 mg/ml: 1 spray in each nostril max. 3 times daily for max. 10 days.

Children 2-10 years:

Nasal spray 0.5 mg/ml: 1 spray in each nostril max. 3 times daily for max. 5 days.

Should not be given to children under the age of 2 without a doctor's recommendation.

Instruction for use:

Always blow the nose before using nose spray.

Remove the protective cap.

Prior to use the first time: Press the pump several times until a fine mist comes out.

Hold the bottle upright.

Bend head slightly forward.

Hold one nostril closed and insert the tip of the spray into the other nostril. Quickly press the pump once while inhaling.

Repeat the process in the other nostril.

4.3 Contraindications

Hypersensitivity to xylometazoline or to any of the excipients.

As for other vasoconstrictors, xylometazoline hydrochloride must not be used after transsphenoidal hypophysectomy or after transnasal/transoral operations in which dura mater is exposed. Presence of narrow-angle glaucoma.

4.4 Special warnings and precautions for use

The warning “nasal spray 0.5 mg/ml and 1 mg/ml should not be given to children under the age of 2 because of risk of overdosing followed by depression of the central nervous system” must always be stated in information about the medicinal product.

The duration of the treatment should not be longer than ten days as long term and frequent use can induce swelling of the nasal mucosa and hypersecretion caused by the increased sensitivity of the cells ("rebound effect").

Xylometazoline must be administered with caution to persons who are sensitive to adrenergic substances that can give symptoms such as insomnia, dizziness, tremor, cardiac arrhythmia or high blood pressure.

Xylometazoline should be used with care and only after physician's instruction in patients with hyperthyroidism, diabetes mellitus, hypertension, arteriosclerosis, aneurysms, ischemic heart disease, arrhythmias and tachycardias, problems with urination due to enlarged prostate, in patients treated with MAO-inhibitors and other medicinal products which can increase the blood pressure as well as in pheochromocytoma.

Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.

4.5 Interaction with other medicinal products and other forms of interaction

If administered simultaneously with tri-cyclic or tetra-cyclic antidepressives or monoamine oxidase inhibitors, a systemic effect of xylometazoline can not be excluded, and the sympathomimetic effects can increase.

4.6 Pregnancy and lactation

Pregnancy

Xylometazoline should not be used during pregnancy because of possible systemic vasoconstrictor action.

Lactation

Xylometazoline can be used during lactation. Should only be used after physician's instruction.

4.7 Effects on ability to drive and use machines

Xylometazoline has no influence on the ability to drive or use machines.

4.8 Undesirable effects

The most common adverse reactions are related to the nose and mucous membranes.
Approx. 3-8 % of the patients will experience an adverse reaction.

Frequency Organ class	Common (≥1/100 to <1/10)	Uncommon (≥1/1000 to <1/100)	Rare (≥1/10.000 to <1/1000)	Very rare (<1/10.000)
Immune system disorders				Systemic allergic reactions
Nervous system disorders				Restlessness, insomnia, tiredness, headache
Eye disorders				Transient disturbed vision
Vascular disorders				Tachycardia or irregular pulse
Respiratory, thoracic and mediastinal disorders	Stinging in the nose and throat, dry and irritated nasal mucosa, sneezing, transient burning sensation, nasal secretion.	Blockage of the nose (reactive hyperaemia), especially after frequent or prolonged use, Epistaxis		
Gastrointestinal disorders			Nausea, vomiting	

4.9 Overdose

In case of overdose or accidental administration through the mouth the clinical picture has been CNS depression with significant reduction of the body temperature, perspiration, drowsiness, headache, increased or irregular pulse, increased blood pressure and potential coma, particularly in children. Rebound hypotension may follow the hypertension.

Treatment: Symptomatic, no specific treatment available.
Medical observation is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alpha-sympathomimetic agent, ATC code: R 01 AA 07.

Xylometazoline hydrochloride is a sympathomimetic agent with alfa-receptor stimulating effect for local administration to the nasal mucosa. Xylometazoline acts vasoconstricting on the nasal mucosa, reducing acute swelling of the mucous membrane, making breathing through the nose and drainage from the nose and sinuses easier. Risk of affecting the heart and central nervous system is very small.

Onset of effect is seen after a few minutes, lasting up to 6-8 hours.

5.2 Pharmacokinetic properties

After local administration, the plasma concentration of xylometazoline in humans is lower than the detection limit.

5.3 Preclinical safety data

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Sodium chloride
Water, purified.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Nasal spray 0.5 mg/ml: 3 years
Nasal spray 1 mg/ml: 3 years.

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

Plastic bottle with spray pump.
Spray pump: Cylinder: polypropylene
Dip tube: polyethylene and polypropylene

Pack sizes: Nasal spray 0.5 mg/ml: 10 ml
Nasal spray 1 mg/ml: 10 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Handling of unused or waste product

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

21 May 2025