

# Xylo Acino™

## Nasal Spray

Decongestant nasal spray

### Composition

Active substances

Xylometazoline hydrochloride.

Excipients

Excipients per nasal spray.

### Galenical form and amount of active substance per unit

Xylo Acino nasal spray without preservative for adults (0.1%)

1 puff corresponds to:

Xylometazoline hydrochloride 0.09 mg.

Xylo Acino nasal spray without preservative for children (0.05%)

1 puff corresponds to:

Xylometazoline hydrochloride 0.045 mg.

### Indications/Possibilities for use

Colds of various types.

For easing the flow of secretions if the paranasal sinuses are affected.

In the case of otitis media as an adjuvant to mucosal decongestant in the nasopharynx.

To facilitate rhinoscopy.

### Dosage/Use

Xylo Acino nasal spray 0.05% for children above 2 years of age

Normally 1 spray in each nostril 1-2 per day is sufficient whereas 3 applications per day should not be exceeded.

Xylo Acino nasal spray 0.1% only for adults and children above 6 years of age

1 spray in each nostril. Repeat if necessary; 3-4 applications per day are usually sufficient.

*How to use the spray:* Remove the dust cap. Before using for the first time pump a few times until an even fine mist is produced. When using again, the metered dosage spray is ready for use immediately. Place the nozzle of the spray into the nostril and press once firmly on the collar of the nozzle; withdraw the spray before releasing the pressure. To ensure optimum distribution of the fine mist you should breathe in gently through your nose while applying the spray. Put the dust cap back on after use.

### Contraindications

Like other vasoconstrictors Xylo Acino should not be used following a transphenoidal hypophysectomy (or any other transnasal or transoral surgical procedure in which the dura mater is exposed) or if you have dry mucosa (rhinitis sicca), closed-angle glaucoma or if you are known to be allergic to the contents.

### Special warnings and special precautions for use

Like all preparations with the same class of active agent, Xylo Acino should only be used with caution for patients with high blood pressure, cardiovascular disease, hyperthyroidism, diabetes mellitus or patients who have an intense reaction to sympathomimetic substances, with evidence of sleeplessness, vertigo, etc. As with other topical vasoconstrictive agents, you should not take Xylo Acino continuously for more than one week, for example for a chronic cold, unless instructed to do so by your doctor, since rhinitis medicamentosa with swelling of the nasal mucosa, which is very similar in its symptoms to a cold, can occur.

### Interactions

If the medication is taken as instructed, any systemic effects are negligible. However, particularly if the stated dosage is exceeded, potential systemic effects of Xylo Acino can be intensified if tricyclic or tetracyclic antidepressants, MAO inhibitors or other medications which potentially increase the blood pressure are taken simultaneously.

### Pregnancy/Lactation

In view of its vasoconstrictive properties, as a precaution Xylo Acino should not be taken during pregnancy. It should be used with caution during breast-feeding. No controlled studies on animals or pregnant women are yet available.

### Effects on ability to drive and use machines

If cold remedies are taken for a long time or they contain a high dose of xylometazoline, systemic effects with cardiovascular events cannot be ruled out.

### Undesirable effects

Respiratory tract

Particularly in sensitive patients Xylo Acino can cause temporary slight irritations (burning or dryness of the nasal mucosa). In individual cases, after the effect has receded, increased mucosal swelling (reactive hyperaemia) may occur. Long-term or frequent use, as well as

high dosage of xylometazoline can lead to intranasal burning and dryness of the mucosa, as well as reactive congestion with rhinitis medicamentosa. This effect can occur after using the medication for just 5-7 days and with continued use can cause lasting damage to the mucosa with crust development.

Nervous system

Very rarely or in individual cases headaches, sleeplessness or tiredness may occur.

Heart and circulation

With topical intranasal application rarely to occasionally systemic sympathomimetic effects such as palpitations, increased pulse rate or increased blood pressure may occur.

Immune system

Very rare cases of allergic reactions with dyspnoea and angioedema.

### Overdosage

No cases of overdosage in adults have yet been reported.

In rare case of accidental intoxication of children the main clinical symptoms have been accelerated and irregular pulse, increase in blood pressure and possibly clouding of consciousness. Symptomatic treatment under medical supervision is recommended.

### Properties/Effects

ATC-Code: R01AA07

Xylometazoline belongs to the arylalkyl imidazole group.

Xylo Acino, which is intended for use in the nose, constricts the blood vessels there, resulting in decongestion of the mucosa in the nose and the surrounding area of the nasopharynx. Xylo Acino thus aids breathing through the nose during colds and rhinitis.

The effect is felt within a few minutes and lasts for up to ten hours. Xylo Acino does not impair the function of the ciliated epithelium.

### Pharmacokinetics

After local application the amount of active agent in the plasma is so low that it cannot be detected with modern methods of analysis.

### Preclinical safety data

No data specific to the preparation are available.

### Further remarks

Xylo Acino should not be used for more than 1 year after first opening of the package.

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use this medication after the expiry date stated «EXP» on the tube and outer box.

### Presentation

Nasal spray 0.05%: Packings of 10 ml

Nasal spray 0.1%: Packings of 10 ml

Not all pack sizes may be marketed.

### Date of information

March 2005

### THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,

Union of Arab Pharmacists.

Manufactured by Merckle, Blaubeuren-Weiler, Germany

for Acino, Liesberg, Basel-Land, Switzerland

Product	Xylo-Acino 0.05%/0.1% Naspr SA (PP) 4	Order No.	4500094319	1. proof	24.05.2013
Material	31184	Fonts	Myriad Pro Condensed	2. proof	31.05.2013
Text-Code	2013	Font Sizes	Adobe Arabic	3. proof	
Pharmacode		Customer	Acino Pharma AG	4. proof	
Dimension	200 x 270 mm				
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