

## **Summary of Product Characteristics**

### **Xylo-Acino 0.05% / 0.1%**

#### **Composition**

*Active substance:* Xylometazoline hydrochloride

*Excipients:* Excipients for solution

#### **Pharmaceutical form and amount of active substance per unit**

Nasal Spray for children with 0.05% xylometazoline hydrochloride in aqueous solution.

1 puff corresponds to 0.045 mg (0.05% solution) xylometazoline hydrochloride.

Nasal Spray for adults with 0.1% xylometazoline hydrochloride in aqueous solution.

1 puff corresponds to 0.09 mg (0.1% solution) xylometazoline hydrochloride.

#### **Indications/Possibilities for use**

Colds of various types.

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

For otitis media as an adjuvant to mucosal decongestant in the nasopharynx.

To facilitate rhinoscopy.

#### **Posology/Administration**

*Nasal Spray 0.05% for children aged 2 years or over*

Normally 1 spray in each nostril 1-2 times per day is sufficient, whereby there should be no more than 3 applications per day.

*Nasal Spray 0.1% only for adults and children aged 6 years or over*

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

*How to use the spray*

Remove the protective cap. Before using for the first time pump a few times until an even, fine mist is produced. For further applications, the metered dosage spray is ready for use immediately. Place the nozzle of the spray into the nostril and press once firmly on the spray head; withdraw the spray nozzle before releasing the pressure. To ensure optimum distribution of the spray mist the patient should breathe in gently through the nose while applying the spray. Put the protective cap back on after use.

## **Contraindications**

Xylo-Acino should not be used following a transsphenoidal 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 where there is known hypersensitivity to the contents.

## **Warnings and precautions**

Xylo-Acino should be used with caution in patients with high blood pressure, cardiovascular disease, hyperthyroidism, diabetes mellitus or patients who have an intense reaction to sympathomimetic substances, with signs of sleeplessness, vertigo, etc. As with other topical vasoconstrictive agents, Xylo-Acino should not be used continuously for more than one week, for example for a chronic cold, unless instructed otherwise by a physician, since rhinitis medicamentosa can occur with swelling of the nasal mucosa, which is very similar in its symptoms to a cold.

## **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 available.

## **Effects on ability to drive and use machines**

If cold remedies containing xylometazoline are taken for a long time or at high doses, 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 doses 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 formation.

#### *Nervous system*

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

#### *Heart and circulation*

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

#### *Immune system*

Very rare cases of allergic reactions with dyspnoea and angioedema.

### **Overdose**

No cases of overdosage in adults have yet been reported.

In rare cases of accidental intoxication in 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

#### *Mechanism of action*

Xylometazoline belongs to the arylalkyl imidazoline 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 begins 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 data**

No data specific to the preparation are available.

### **Further remarks**

*Shelf life: 36 months*

Xylo-Acino may only be used up to the date marked with “EXP” on the container.

*Storage conditions*

Do not store above 25°C.

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

Xylo-Acino has a shelf life of 12 months after opening the Nasal Spray.

**Marketing Authorisation Number**

41-222-10

42-222-10

**Presentation**

Xylo-Acino 0.05% Nasal Spray without preservatives for children: 10 mL Nasal Spray

Xylo-Acino 0.1% Nasal Spray without preservatives for adults: 10 mL Nasal Spray

Not all presentations may be marketed.

**Marketing Authorisation Holder**

Acino Pharma AG, Liesberg

**Date of information**

April 2014

**To report any side effect(s):**

• **Saudi Arabia**

- The National Pharmacovigilance and Drug Safety Centre (NPC)
  - Fax: +966-11-205-7662
  - Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340
  - Toll free phone: 8002490000
  - E-mail: npc.drug@sfd.gov.sa
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