

ingbo Voice Biochemic Co., Ltd.

Contact email: info@pharma-voice.com

Tel/Fax: 0086 574 87330957

This information is intended for use by health professionals

1. Name of the medicinal product

Xylometazoline Nasal Drops 0.1% 10ml

2. Qualitative and quantitative composition

Xylometazoline Hydrochloride 0.1% w/v

For excipients see 6.1.

3. Pharmaceutical form

Nasal drops, solution ; The product is a clear, colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

For the symptomatic relief of nasal congestion, perennial and allergic rhinitis (including hay fever), sinusitis.

4.2 Posology and method of administration

Adults and elderly (all indications): 2 or 3 drops in each nostril 2 or 3 times daily.

The drops are suitable for children over 12 years of age.

Route of administration: Nasal use.

4.3 Contraindications

Known hypersensitivity to Xylometazoline.

Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.

4.4 Special warnings and precautions for use

Patients are advised not to take decongestants for more than seven consecutive days. Xylometazoline, like other preparations belonging to the same class of active substances, should be used only with caution in patients showing a strong reaction to sympathomimetic agents as evidenced by signs of insomnia, dizziness etc.

Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism, narrow angle glaucoma or diabetes mellitus.

Label warnings and precautions

- Do not exceed the stated dose
- Do not use continuously for more than seven consecutive days. If symptoms persist, consult your doctor
- If you are pregnant or taking other medicines or are under a doctor's care, consult your doctor before using Xylometazoline
- Not to be used for infants or children under 12 years
- Each Xylometazoline pack should be used by one person only to prevent any cross infection
- For reasons of hygiene do not use this bottle for more than 28 days after first opening it
- Keep medicines out of the reach of children

Additional leaflet warnings and precautions

- Do not use if you are sensitive to any of the ingredients of Xylometazoline
- Do not use if you have had recent neurosurgery
- Consult your doctor before using Xylometazoline if you have heart or circulatory disease
- Some patients who have sensitive nasal passages may feel some local discomfort when applying the product.
- Other side effects such as palpitations, nausea and headache are very rare

4.5 Interaction with other medicinal products and other forms of interaction

As for all sympathomimetics, a reinforcement of the systemic effects of xylometazoline by concomitant use of monoamine oxidase inhibitors, tricyclic or tetracyclic antidepressants, cannot be excluded, especially in case of overdose.

4.6 Fertility, pregnancy and lactation

No foetal toxicity or fertility studies have been carried out in animals. In view of its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using Xylometazoline during pregnancy.

Label warning: If you are pregnant or taking any other medicines, or are under a doctor's care, consult him before using Xylometazoline.

No evidence of any adverse effect on the breast-fed infant. However, it is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and Xylometazoline should be used only on the advice of a doctor whilst breastfeeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following side effects have occasionally been encountered: A burning sensation in the nose and throat, local irritation, nausea, headache and dryness of the nasal mucosa.

Systemic cardiovascular effects have occurred, and this should be kept in mind when giving Xylometazoline to people with cardiovascular disease. In isolated cases, systemic allergic reactions and transient visual disturbances.

4.9 Overdose

In rare instances of accidental poisoning in children, the clinical picture has been marked chiefly by signs such as acceleration and irregularity of the pulse, elevated blood pressure and sometimes consciousness clouding.

There is no specific treatment. Appropriate supportive measures should be initiated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Xylometazoline Nasal Drops is a sympathomimetic agent with marked alpha- adrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Xylometazoline Nasal Drops begins within a few minutes and lasts for up to 10 hours. Xylometazoline Nasal Drops is generally well tolerated and does not impair the function of ciliated epithelium.

5.2 Pharmacokinetic properties

Systemic absorption may occur following nasal application of xylometazoline hydrochloride solutions. It is not used systemically.

5.3 Preclinical safety data

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Disodium edetate ; Sodium dihydrogen phosphate dihydrate (Sodium acid phosphate); Sodium chloride ; Sorbitol ; Hypromellose ; Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened: 36 months

After the container is opened for the first time: 28 days

6.4 Special precautions for storage

Protect from heat.

6.5 Nature and contents of container

Pack size: 10 ml per bottle, 10bottle per box.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

Ningbo Voice Biochemic Co., Ltd.

298 West Zhongshan Road, Ningbo, P.R. China