

Xylomet[®] Nasal Drops

Xylometazoline HCL

Description

Xylometazoline is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use in the nose. It is generally well tolerated and does not impair the function of ciliated epithelium. Systemic absorption may occur following nasal application of Xylometazoline.

Mode of action

Xylometazoline has alpha-adrenergic activity, and constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighboring regions of the pharynx.

Pharmacokinetics

It acts directly on nasal mucosa. Absorption into the nasal mucosal tissues is rapid. Little information is available concerning the distribution, metabolism and elimination of xylometazoline in human.

Composition

Xylomet[®] 0.1% Nasal Drops: Each ml contains Xylometazoline hydrochloride BP 1 mg.

Indications

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

Dosage & administration

Adults: 2 or 3 drop of Xylometazoline Adult formula (0.1%) two to three times daily. Xylometazoline adult formula should not be used for children under the age of 12 years.

Children under 12 years: 1 or 2 drop of the Xylometazoline children's formula (0.05%) in each nostril once or twice daily. Not to be used in infants less than 3 months.

For stuffy nose:

For nasal solution (nose drops) dosage forms:

Adults and children 12 years of age and older: Use one to three drops or drops of a 0.1% solution in each nostril every eight to ten hours as needed.

Children 2 to 12 years of age: Use two or three drops or drops of a 0.05% solution in each nostril every eight to ten hours as needed.

Children up to 2 years of age: Use and dose must be determined by your doctor.

The following dosage guidelines are used in Canada for children up to 12 years of age:

Children 6 to 12 years of age: Use two or three drops or drops of a 0.05% solution in each nostril every eight to ten hours as needed.

Children up to 6 years of age: Use one drop or drops of a 0.05% solution in each nostril every eight to ten hours as needed.

Contraindications

Xylometazoline is contraindicated in patients with transsphenoidal hypophysectomy or surgery exposing the dura mater. It is also contraindicated in patients who are hypersensitive to Xylometazoline.

Use in pregnancy & lactation

No fetal 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.

Side 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.

Precautions:

Xylometazoline should be used by one person only to prevent any cross-infection. Patients are advised not to take decongestants for more than seven consecutive days.

Drug interactions

No drug interactions have been reported.

Over dosage

Excessive dosage and/or prolonged or too frequent use of Xylometazoline may irritate nasal mucosa and especially in children. Excessive dosage in children may cause profound CNS depression, shock like hypotension. Symptoms of a Xylometazoline nasal overdose include extreme tiredness, sweating, dizziness, a slow heartbeat, and coma.

Storage

Store in a cool and dry place, protected from light.

Packaging

Xylomet[®] 0.1% Nasal Drops: Each amber glass container contains 15 ml.



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