

XYLOMETAZOLINE (Nasal)

Introduction

VA CLASSIFICATION (Primary) NT100

Commonly used brand name(s): Decongest Nasal Spray; Inspire Nasal Spray; Inspire Nasal Spray M-D Pump; Otrivin Measured-Dose Pump with Moisturizers; Otrivin Nasal Drops; Otrivin Nasal Spray; Otrivin Nasal Spray with Eucalyptol; Otrivin Nasal Spray with Moisturizers; Otrivin Pediatric Nasal Drops; Otrivin Pediatric Nasal Spray; Otrivin With Measured-Dose Pump.

Note: For a listing of dosage forms and brand names by country availability, see Dosage Forms section(s).

Category

Decongestant (topical).

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Congestion, nasal (treatment) Xylometazoline is indicated for the temporary relief of nasal congestion due to colds, sinusitis, hay fever, other upper respiratory allergies (allergic rhinitis) 1, 2, 3, 4, 7 and for headache, tubal block, and serious otitis media associated with nasal congestion. 6

[Congestion, sinus (treatment)] Nasal xylometazoline is used for the relief of sinus congestion.

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Molecular weight 280.84 9

Mechanism of action/Effect:

A direct-acting sympathomimetic amine. Xylometazoline acts on alpha-adrenergic receptors in the nasal mucosa to produce vasoconstriction, resulting in decreased blood flow and decreased nasal congestion.

Duration of action:

Up to 10 hours.

Precautions to Consider

Cross-sensitivity and/or related problems

Patients sensitive to other nasal decongestants may be sensitive to this medication also.

Pregnancy/Reproduction

Pregnancy¾Adequate and well-controlled studies in humans have not been done. 3, 4, 6

FDA Pregnancy Category C. 8

Breast-feeding

It is not known whether xylometazoline is distributed into breast milk. However, problems in humans have not been documented. 4, 6

Pediatrics

Children may be especially prone to systemic absorption of xylometazoline with resulting side effects, especially sedation 6.

Geriatrics

Appropriate studies on the relationship of age to the effects of xylometazoline have not been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)¾not necessarily inclusive (>> = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

Antidepressants, tricyclic or

Monoamine oxidase (MAO) inhibitors 6, 8 or

Maprotiline 10

(if significant systemic absorption of nasal xylometazoline occurs, concurrent use of maprotiline, monoamine oxidase (MAO) inhibitors, or tricyclic antidepressants may potentiate the pressor effect of xylometazoline)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate) % not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problems exist 1, 2, 3, 4, 6, 7

Coronary artery disease or

Heart disease, including angina or

Hypertension

(condition may be exacerbated due to drug-induced cardiovascular effects)

Enlarged prostate

(urination difficulty may worsen due to drug-induced cardiovascular effects)

Diabetes mellitus or

>> Glaucoma, narrow-angle, predisposition to

(vasoconstriction may be exacerbated due to drug-induced cardiovascular effects)

Hyperthyroidism

Sensitivity to xylometazoline or other nasal decongestants

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate) %not necessarily inclusive:

Those indicating need for medical attention

Rebound congestion (increase in runny or stuffy nose) 1, 2, 3, 4, 6, 7

Symptoms of systemic absorption

Allergic reaction or hypersensitivity (hives; rash; shortness of breath; swelling of eyelids, face, or lips; troubled breathing; wheezing); blurred vision; dizziness; headache or lightheadedness; nausea; nervousness; pounding, irregular, or fast heartbeat; trouble in sleeping 6

Those indicating need for medical attention only if they continue or are bothersome

Burning, dryness, or stinging of nasal mucosa; increase in nasal discharge; sneezing 1, 2, 3, 4, 6, 7

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Xylometazoline (Nasal).
In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Sensitivity to xylometazoline or other nasal decongestants

Use in children¾Children may be especially prone to systemic absorption of nasal xylometazoline and resulting side/adverse effects, especially sedation

Other medical problems, especially predisposition to narrow-angle glaucoma

Proper use of this medication

Proper administration technique

Preventing contamination

Replacing cap right after use

For nose drops¾Rinsing dropper with hot water; drying with a clean tissue

For nose spray¾Rinsing tip of spray bottle with hot water, taking care not to suck water into bottle; drying with a clean tissue

Preventing spread of infection: Not using container for more than one person

1, 2, 3

>> Importance of not using more medication than the amount recommended

>> Proper dosing

Missed dose: Using right away if remembered within an hour or so; not using if remembered later; not doubling doses

>> Proper storage

Side/adverse effects

Signs of potential side effects, especially rebound congestion and sympathomimetic systemic effects

General Dosing Information

Prolonged or excessive use of this medication, i.e., for more than 3 days, will cause rebound congestion with chronic swelling of nasal mucosa. 1, 2, 3, 4, 7

Medication is more effective if 3 to 5 minutes are allowed to elapse between each spray per nostril, and nose is blown thoroughly before next spray is administered. Continue until complete dose is used.

Nasal Dosage Forms

XYLOMETAZOLINE HYDROCHLORIDE NASAL SOLUTION USP

Usual adult and adolescent dose

Decongestant, topical^{3/4}

Intranasal, 1 to 3 drops or sprays of a 0.1% solution into each nostril every eight to ten hours as needed.

Usual adult and pediatric prescribing limits

Maximum of 3 doses per day.

Note:

The nasal solution form of the medication is more effective and less likely to cause systemic absorption. Usual pediatric dose

Note: The 0.1% solutions are not recommended for use in children up to 12 years of age. 1, 3, 4, 6, 7

Decongestant, topical^{3/4}

Children up to 2 years of age: Dosage must be individualized by physician. 2, 7

Children 2 to 12 years of age: Intranasal, 2 or 3 drops or sprays of a 0.05% solution into each nostril every eight to ten hours as needed.

Children 12 years of age and older: See Usual adult and adolescent dose

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

Children up to 6 years of age: Intranasal, 1 drop or spray of a 0.05% solution into each nostril every eight to ten hours as needed.

Children 6 to 12 years of age: Intranasal, 2 or 3 drops or sprays of a 0.05% solution into each nostril every eight to ten hours as needed.

Usual pediatric prescribing limits

Maximum of 3 doses per day.

Strength(s) usually available

U.S. 0.05% (nasal drops) (OTC)[Otrivin Pediatric Nasal Drops 2, 7 (benzalkonium chloride) (dibasic sodium phosphate) (disodium edetate) (monobasic sodium phosphate) (sodium chloride)]

0.1% (nasal drops) (OTC)[Otrivin Nasal Drops 7 (benzalkonium chloride) (dibasic sodium phosphate) (disodium edetate) (monobasic sodium phosphate) (sodium chloride)]

0.1% (nasal spray) (OTC)[Otrivin Nasal Spray 1, 7 (benzalkonium chloride) (dibasic sodium phosphate) (disodium edetate) (monobasic sodium phosphate) (sodium chloride)] [Inspire Nasal

Spray 3 (aloe vera) (benzalkonium chloride) (polysorbate 20) (potassium chloride) (potassium phosphate monobasic) (sodium chloride) (sodium phosphate dibasic) (vitamin E)] [Inspire Nasal Spray M-D Pump 4 (aloe vera) (benzalkonium chloride) (polysorbate 20) (potassium chloride) (sodium chloride) (sodium phosphate dibasic) (vitamin E)]

Canada 0.05% (nasal drops) (OTC)[Otrivin Pediatric Nasal Drops 6 (benzalkonium chloride) (edetate disodium) (sodium chloride) (sodium phosphate)]

0.05% (nasal spray) (OTC)[Otrivin Pediatric Nasal Spray 6 (benzalkonium chloride) (edetate disodium) (sodium chloride) (sodium phosphate)]

0.1% (nasal drops) (OTC)[Otrivin Nasal Drops 6 (benzalkonium chloride) (edetate disodium) (sodium chloride) (sodium phosphate)]

0.1% (nasal spray) (OTC)[Decongest Nasal Spray 5 (benzalkonium chloride) (EDTA disodium) (potassium chloride) (potassium phosphate dibasic) (sodium chloride) (sodium phosphate monobasic)] [Otrivin Measured-Dose Pump with Moisturizers 6] [Otrivin Nasal Spray 6 (benzalkonium chloride) (edetate disodium) (sodium chloride) (sodium phosphate)] [Otrivin Nasal Spray with Eucalyptol 6] [Otrivin Nasal Spray with Moisturizers 6] [Otrivin With Measured-Dose Pump 6]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container. Protect from freezing. 1, 2, 3, 4, 7

Stability:

Do not use aluminum-containing apparatus to store or apply medication since medication is degraded in the presence of aluminum.

Auxiliary labeling:

- For the nose.