

OXYMETAZOLINE (Nasal)

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)¼Oxymetazoline is indicated for temporary relief of nasal congestion, up to 12 hours, due to the common cold, sinusitis, hay fever, or other upper respiratory allergies (allergic rhinitis). 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

[Congestion, sinus (treatment)]¼Nasal oxymetazoline is used for the relief of sinus congestion. 7.

Precautions to Consider

Cross-sensitivity and/or related problems

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

Pregnancy/Reproduction

Oxymetazoline may be systemically absorbed. However, adequate and well-controlled studies in humans have not been done. 7

Breast-feeding

Oxymetazoline may be systemically absorbed. However, problems in humans have not been documented.

Pediatrics

Children may be especially prone to systemic absorption of oxymetazoline with resulting side/adverse effects.

Geriatrics

Although appropriate studies on the relationship of age to the effects of oxymetazoline have not been performed in the geriatric population, 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)¼not 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 7 or

Maprotiline or

Monoamine oxidase inhibitors 5, 6, 7

(if significant systemic absorption of nasal oxymetazoline occurs, concurrent use may potentiate the pressor effect of oxymetazoline)

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)¼ not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problems exist

Coronary artery disease or

Heart disease, including angina or

Hypertension

(condition may be exacerbated due to drug-induced cardiovascular effects 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 21, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48)

Enlarged prostate

(difficulty of urination due to enlarged prostate may be exacerbated because of vasoconstrictive effects 1, 2, 4, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48)

Diabetes mellitus 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Glaucoma, narrow angle 5, 6, 7

Hyperthyroidism 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Rhinitis, sicca 5, 6, 7

(may exacerbate already dry mucous membranes)

Sensitivity to oxymetazoline or other nasal decongestants 5, 6, 7

(may exacerbate side effects such as, sleepiness, dizziness, lightheadedness, weakness, tremulousness or cardiac arrhythmia)

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 1, 2, 4, 5, 6, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 37, 38, 45, 47, 48 (increase in runny or stuffy nose)

Symptoms of systemic absorption 7

Blurred vision 5, 6; fast, irregular, or pounding heartbeat; headache, dizziness, drowsiness, or lightheadedness; high blood pressure 5, 6; nervousness 5, 6; trembling; trouble in sleeping; weakness
Those indicating need for medical attention only if they continue or are bothersome

Burning, dryness, or stinging of nasal mucosa 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 45, 47, 48; increase in nasal discharge 1, 2, 4, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 45, 47, 48; sneezing 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 45, 47, 48

Overdose

In children, oxymetazoline may produce profound central nervous system depression. For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center listing). 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 15, 16, 18, 20, 21, 22, 36, 45

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Oxymetazoline (Nasal).

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Sensitivity to oxymetazoline or other nasal decongestants

Pregnancy %Oxymetazoline may be systemically absorbed

Breast-feeding %Oxymetazoline may be systemically absorbed

Use in children %Children may be especially sensitive to the effects of oxymetazoline

Other medications, especially maprotiline, monoamine oxidase inhibitors, and tricyclic antidepressants

Other medical problems, especially coronary artery disease, diabetes mellitus, enlarged prostate, heart disease, hypertension, hyperthyroidism, open-angle glaucoma, and rhinitis sicca

Proper use of this medication

Proper administration technique

Preventing contamination: Wiping tip of applicator with clean, damp tissue; replacing cap right after use

Preventing spread of infection: Not using bottle for more than 1 person

>> Importance of not using more medication than the amount recommended; not using medication for more than 3 days without checking with physician

>> Proper dosing

Missed dose: If on scheduled dosing regimen, use right away if remembered within an hour or so; if not remembered until later, skipping missed dose and returning to regular dosing schedule; not doubling doses

>> Proper storage

Side/adverse effects

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

General Dosing Information

Prolonged or excessive use of this medication will cause rebound congestion with chronic swelling of nasal mucosa.

Nasal Dosage Forms

OXYMETAZOLINE HYDROCHLORIDE NASAL SOLUTION USP

Usual adult and adolescent dose

Decongestant

Intranasal, 2 or 3 drops or sprays of a 0.05% solution into each nostril every ten to twelve hours. 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Note: The nasal spray form of the medication is more effective and less likely to cause systemic absorption.

Usual adult and adolescent prescribing limits

Maximum of 2 doses in twenty four hours. 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Usual pediatric dose

Decongestant^{3/4}

Children up to 6 years of age: Dosage has not been established. 1, 2, 4, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Children 6 years of age and older: See Usual adult and adolescent dose. 1, 2, 7, 8, 9, 10, 11, 12, 13, 14, 16, 18, 20, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Usual pediatric prescribing limits

Maximum of 2 doses in twenty four hours. 1, 2, 7, 8, 9, 10, 11, 12, 13, 14, 16, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38, 39, 40, 45, 47, 48

Strength(s) usually available

U.S.^{3/4}0.05% (nasal drops) (OTC)[Afrin Original 12 Hour Nose Drops 8, 34, 41 (benzalkonium chloride) (edetate disodium) (polyethylene glycol 1450) (povidone) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (water)] [Generic]

0.05% (nasal spray) (OTC)[Afrin Cherry 12 Hour Nasal Spray 9, 38, 41 (artificial cherry flavor) (benzalkonium chloride) (benzyl alcohol) (edetate disodium) (polyethylene glycol 1450) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (water)] [Afrin Extra Moisturizing 12 Hour Nasal Spray 1, 28, 41 (benzalkonium chloride) (edetate disodium) (sodium phosphate dibasic) (sodium phosphate monobasic) (Soothateä [glycerin, polyethylene glycol 1450, propylene glycol]) (water)] [Afrin Original 12 Hour Nasal Spray 12, 33, 41 (benzalkonium chloride) (edetate disodium) (polyethylene glycol 1450) (povidone) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (water)] [Afrin Original 12 Hour Pump Mist 18, 35, 41 (benzalkonium chloride) (edetate disodium) (polyethylene glycol 1450) (povidone) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (water)] [Afrin Sinus 12 Hour Nasal Spray 2, 37, 41 (benzalkonium chloride) (benzyl alcohol) (edetate disodium) (polysorbate 80) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (Vapornaseä [camphor, eucalyptol, menthol]) (water)] [Dristan 12-Hr Nasal Spray 21, 30 (benzalkonium chloride) (dibasic sodium phosphate) (hydroxypropyl methylcellulose) (monobasic potassium phosphate) (purified water) (sodium chloride) (thimerosal)] [Duramist Plus Up To 12 Hour Nasal Decongestant Spray 36, 44 (benzalkonium chloride) (glycerin) (potassium phosphate) (sodium chloride) (sodium phosphate)] [Duration 12 Hour Nasal Spray 11, 42, 45 (benzalkonium chloride) (edetate disodium) (polyethylene glycol 1450) (povidone) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (water)] [Genasal Nasal Spray Up to 12 Hour Relief 13, 43 (benzalkonium chloride) (edetate disodium) (polyethylene glycol 1450) (povidone) (propylene glycol) (sodium phosphate dibasic) (sodium phosphate monobasic) (water)] [Nasal Relief 12 Hour Nasal Spray 15, 46 (benzalkonium chloride) (disodium edetate) (disodium phosphate) (monosodium phosphate) (phenylmercuric acetate 0.02%) (purified water) (sorbitol)] [Neo-Synephrine 12 Hour Extra Moisturizing Spray 16, 26, 39 (benzalkonium chloride) (glycerin) (glycine) (phenylmercuric acetate) (purified water) (sodium chloride) (sorbitol)] [Neo-Synephrine 12 Hour Spray 14, 26, 40 (benzalkonium chloride) (glycerin) (glycine) (phenylmercuric acetate) (purified water) (sodium chloride) (sorbitol)] [Nostrilla 12 Hour Nasal Decongestant 4, 27] [Twice-A-Day Extra Moisturizing 12 Hour Nasal Spray 20, 23 (benzalkonium chloride) (glycerin) (purified water) (sodium chloride) (sodium phosphate dibasic) (sodium phosphate monobasic)] [Twice-A-Day Soothing 12 Hour Nasal Spray 22, 23 (benzalkonium chloride) (purified water) (sodium chloride) (sodium phosphate dibasic) (sodium phosphate monobasic)] [Vicks Sinex 12 Hour Nasal Spray 25, 47] [Vicks Sinex 12 Hour Ultra Fine Mist for Sinus Relief 25, 48

(aromatic vapors [camphor, eucalyptol, menthol]) (benzalkonium chloride) (chlorhexidine gluconate) (disodium EDTA) (potassium phosphate) (purified water) (sodium chloride) (sodium phosphate) (tyloxapol)] [4-Way 12-Hour Nasal Spray 10, 19 (benzalkonium chloride) (glycine) (phenylmercuric acetate 0.002%) (sorbitol) (water)] [Generic] 29, 31, 51

Canada 0.05% (nasal spray) (OTC)[Dristan Long Lasting Nasal Mist 5 (benzalkonium chloride) (cellulose) (potassium phosphate) (purified water) (sodium chloride) (sodium phosphate) (thimerosal)] [Dristan Long Lasting Mentholated Nasal Spray 6 (alcohol) (camphor) (cellulose) (eucalyptol) (menthol) (potassium phosphate) (purified water) (sodium chloride) (sodium phosphate) (thimerosal)] [Drixoral Nasal Solution 7 (water)]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 2 and 30 °C (36 and 86 °F), unless otherwise specified by manufacturer 2, 4, 9, 11, 15, 18, 20, 21, 22, 28, 33, 34, 35, 36, 37, 38.

Store in a tight container. Protect from freezing. Protect from light. 16

Auxiliary labeling:

- For the nose.

References

1 Afrin extra moisturizing 12 hour nasal spray package labeling (Schering-Plough[®]US), Rec 5/13/99.

2 Afrin sinus 12 hour nasal spray package labeling (Schering-Plough[®]US), Rec 5/13/99.

3 Open.

4 Nostrilla 12 hour nasal decongestant package labeling (Heritage[®]US), Rec 5/19/99.

5 Dristan long lasting nasal mist (Whitehall-Robins). In: Gillis MC, editor. CPS Compendium of pharmaceuticals and specialties. 34th ed. Ottawa: Canadian Pharmacists Association; 1999. p. 556.

6 Dristan long lasting mentholated nasal spray (Whitehall-Robins). In: Gillis MC, editor. CPS Compendium of pharmaceuticals and specialties. 34th ed. Ottawa: Canadian Pharmacists Association; 1999. p. 556.

7 Drixoral Nasal Solution (Schering). In: Gillis MC, editor. CPS Compendium of pharmaceuticals and specialties. 34th ed. Ottawa: Canadian Pharmacists Association; 1999. p. 558.

8 Afrin original 12 hour nose drops package labeling (Schering-Plough[®]US), Rec 5/13/99.

9 Afrin cherry 12 hour nasal spray package labeling (Schering-Plough[®]US), Rec 5/13/99.

10 4-Way 12 Hour Nasal Spray package labeling (Bristol-Myers Squibb[®]US), Rec 6/9/99.

11 Duration 12 hour nasal spray package labeling (Schering-Plough[®]US), Rec 5/13/99.

- 12 Afrin original 12 hour nasal spray package labeling (Schering-Plough%US), Rec 5/13/99.
- 13 Genasal nasal spray up to 12 hour relief package labeling (Zenith Goldline%US), Rec 5/7/99.
- 14 Neo-synephrine 12 hour spray package labeling (Bayer%US), Rec 5/7/99.
- 15 Nasal relief package labeling (Altaire%US), Rec 5/19/99.
- 16 Neo-synephrine 12 hour extra moisturizing spray package labeling (Bayer%US), Rev 12/9/97, Rec 5/10/99.
- 17 Open.
- 18 Afrin original 12 hour pump mist package labeling (Schering-Plough%US), Rec 5/13/99.
- 19 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Bristol-Myers) p. 614.
- 20 Twice-A-Day extra moisturizing 12 hour nasal spray package labeling (Major%US), Rec 5/10/99.
- 21 Dristan 12-hour nasal spray package labeling (Whitehall-Robins%US), Rec 5/7/99.
- 22 Twice-A-Day soothing 12 hour nasal spray package labeling (Major%US), Rec 5/10/99.
- 23 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Major) p. 876.
- 24 Lacy CF, Armstrong LL, Ingram NB, et al. editors. APhA Drug information handbook. 6th ed. Hudson, OH: Lexi-Corp Inc; 1998. p. 941.
- 25 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Procter & Gamble) p. 887.
- 26 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Bayer) p. 787.
- 27 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Heritage) p. 793.
- 28 Afrin extra moisturizing 12 hour nasal spray (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 754-5.
- 29 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. p. 614.
- 30 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Whitehall-Robins) p. 701.
- 31 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. p. 802.
- 32 Canada JR, editor. USP dictionary of USAN and international drug names 1998. Rockville, MD: The United States Pharmacopeial Convention Inc; 1997. p. 542.

- 33 Afrin original 12 hour nasal spray (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 754-5.
- 34 Afrin original 12 hour nose drops (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 754-5.
- 35 Afrin original 12 hour pump mist (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 754-5.
- 36 Duramist Plus Up to 12 Hour Nasal Decongestant Spray package labeling (Pfeiffer[®]US), Rec 5/28/99.
- 37 Afrin sinus 12 hour nasal spray (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 754-5.
- 38 Afrin cherry 12 hour nasal spray (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 754-5.
- 39 Neo-syneprine maximum strength 12 hour extra moisturizing nasal spray (Bayer). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 619.
- 40 Neo-Syneprine 12 hour (Bayer). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 619.
- 41 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Schering-Plough) p. 624.
- 42 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Schering-Plough) p. 703.
- 43 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Zenith Goldline) p. 726.
- 44 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Pfeiffer) p. 703.
- 45 Duration 12 hour nasal spray (Schering-Plough). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 763.
- 46 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. (Altaire) p. 786.
- 47 Vicks Sinex 12-hour nasal spray (Procter & Gamble). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 749.
- 48 Vicks Sinex 12-hour ultra fine mist for sinus relief (Procter & Gamble). In: PDR Physicians' desk reference for nonprescription drugs. 19th ed. Montvale, NJ: Medical Economics Co Inc; 1998. p. 749.
- 49 Open.
- 50 Open.
- 51 Red Book 1999. Montvale, NJ: Medical Economics Co Inc; 1999. p. 614.

52 Open.

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