

PHENYLEPHRINE (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)³/₄Nasal phenylephrine is indicated for the symptomatic relief of nasal congestion due to the common cold or hay fever, sinusitis, or other upper respiratory allergies. 21

[Congestion, sinus (treatment)]³/₄Nasal phenylephrine is used for relief of sinus congestion.

Congestion, eustachian tube (treatment)³/₄Nasal phenylephrine may be useful in the adjunctive therapy of middle ear infections by decreasing congestion around the eustachian ostia.

Pharmacology

Mechanism of action/Effect:

Phenylephrine is primarily a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in the arterioles of the nasal mucosa to produce constriction, resulting in decreased nasal congestion.

Precautions to Consider

Cross-sensitivity and/or related problems

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

Pregnancy/Reproduction

Pregnancy³/₄Problems in humans have not been documented; however, nasal phenylephrine may be systemically absorbed.

Breast-feeding

Problems in humans have not been documented; however, nasal phenylephrine may be systemically absorbed.

Pediatrics

Children may be especially prone to systemic absorption of nasal phenylephrine and resulting side/adverse effects. 3, 4

Geriatrics

Appropriate studies on the relationship of age to the effects of phenylephrine 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)³not 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

Maprotiline or

Monoamine oxidase (MAO) inhibitors, including furazolidone, procarbazine, and selegiline

(if significant systemic absorption of nasal phenylephrine occurs, concurrent use of these medications may potentiate the pressor effect of phenylephrine; nasal phenylephrine should not be administered within 14 days following the administration of MAO inhibitors)

Guanadrel or

Guanethidine

(if significant systemic absorption of nasal phenylephrine occurs, concurrent use of guanadrel or guanethidine may potentiate the pressor effect of phenylephrine, possibly resulting in hypertension and/or cardiac arrhythmias)

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)⁴ 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 because of drug-induced cardiovascular effects 21)

Diabetes mellitus 21

Hyperthyroidism 21

Sensitivity to phenylephrine 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)¾not necessarily inclusive:

Those indicating need for medical attention

Rebound congestion (increase in runny or stuffy nose)

Symptoms of systemic absorption

Fast, irregular, or pounding heartbeat; headache or dizziness; increased sweating; nervousness; paleness; trembling; trouble in sleeping

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

Burning, dryness, or stinging of nasal mucosa 21

Patient Consultation

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

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

Before using this medication

>> Conditions affecting use, especially:

Sensitivity to phenylephrine or other nasal decongestants

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

Proper use of this medication

Proper administration technique

Preventing contamination:

Replacing cap right after use

For nasal drops

After using¾Rinsing dropper with hot water and drying with clean tissue

For nasal spray

After using¾Rinsing tip of spray bottle with hot water, taking care not to suck water into bottle, and drying with clean tissue

For nasal jelly

After using¾Wiping tip of tube with clean, damp tissue

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

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

>> Proper dosing

Missed dose: If on scheduled dosing regimen¾Using 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 will cause rebound congestion with chronic swelling of nasal mucosa.

To reduce the chance of rebound congestion and systemic side effects, the weakest strength that is effective should be used.

Nasal Dosage Forms

PHENYLEPHRINE HYDROCHLORIDE NASAL JELLY USP

Usual adult and adolescent dose

Decongestant, topical¾

Intranasal, a small quantity of a 0.5% jelly placed into each nostril and sniffed well back into the nasal passages every three or four hours as needed.

Usual pediatric dose

Pediatric strength not available.

Strength(s) usually available

U.S.¾0.5% (OTC)[Neo-Synephrine Nasal Jelly]

Canada¾Not commercially available.

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 container. Protect from light. Protect from freezing.

Stability:

Prolonged exposure to air, strong light, or heat results in oxidation and some loss of potency. Do not use if jelly is brown.

Incompatibilities:

Medication is incompatible with butacaine, alkalies, ferric salts, oxidizing agents, and metals.

Auxiliary labeling:

- For the nose.

PHENYLEPHRINE HYDROCHLORIDE NASAL SOLUTION USP

Usual adult and adolescent dose

Decongestant, topical^{3/4}

Intranasal, 2 or 3 drops or sprays of a 0.25 to 0.5% solution into each nostril every four hours as needed
5, 10, 19, 20, 21

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

In cases of extreme nasal congestion, the 1% solution may be used initially. 17, 18

Usual pediatric dose

Decongestant, topical^{3/4}

Infants and children up to 2 years of age: Dosage must be individualized by physician.

Children 2 to 6 years of age: Intranasal, 2 or 3 drops of a 0.125 or 0.16% solution into each nostril every four hours as needed. 22, 25

Children 6 to 12 years of age: Intranasal, 2 or 3 drops or sprays of a 0.25% solution into each nostril every four hours as needed. 10, 19

Children 12 years of age and over: See Usual adult and adolescent dose. 5, 17, 18, 20

Strength(s) usually available

U.S. 0.125% (drops) (OTC)[Neo-Synephrine Pediatric Nasal Drops]

0.16% (drops) (OTC)[Alconeprin Nasal Drops 12]

0.2% (drops) (OTC)[Rhinall-10 Children's Flavored Nose Drops]

0.25% (drops) (OTC)[Alconefrin Nasal Drops 25] [Doktors] [Neo-Synephrine Nasal Drops] [Rhinall]
[Generic]

0.25% (spray) (OTC)[Alconefrin Nasal Spray 25] [Doktors] [Neo-Synephrine Nasal Spray] [Nostril Spray
Pump Mild] [Rhinall]

0.5% (drops) (OTC)[Alconefrin Nasal Drops 50] [Neo-Synephrine Nasal Drops]

0.5% (spray) (OTC)[Duration] [Neo-Synephrine Nasal Spray] [Nostril Spray Pump] [Vicks Sinex] [Generic]

1% (drops) (OTC)[Neo-Synephrine Nasal Drops]

1% (spray) (OTC)[Neo-Synephrine Nasal Spray] [Generic]

Canada%0.25% (drops) (OTC)[Neo-Synephrine Nasal Drops]

0.25% (spray) (OTC)[Neo-Synephrine Nasal Spray]

0.5% (drops) (OTC)[Neo-Synephrine Nasal Drops]

0.5% (spray) (OTC)[Neo-Synephrine Nasal Spray]

1% (drops) (OTC)[Neo-Synephrine Nasal Drops]

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.

Stability:

Prolonged exposure to air, strong light, or heat results in oxidation and some loss of potency. Do not use
if solution is brown or contains a precipitate.

Incompatibilities:

Medication is incompatible with butacaine, alkalies, ferric salts, oxidizing agents, and metals.

Auxiliary labeling:

- For the nose.