

TYZINE®

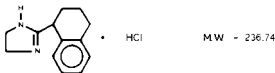
R_x Only

(tetrahydrozoline hydrochloride)

NASAL SOLUTION

DESCRIPTION:

Tyzine® Nasal Solution contains tetrahydrozoline hydrochloride, 2-(1,2,3,4-Tetrahydro-1, naphthyl)-2-imidazoline monohydrochloride, as a nasal decongestant. The chemical structure is:



Nasal Solution is available for topical nasal application as 0.1% nasal solution and as 0.05% pediatric nasal drops. The nasal solution is a solution of tetrahydrozoline hydrochloride in water, with sodium chloride, sodium citrate, edetate disodium, and benzalkonium chloride, with hydrochloric acid to adjust to the pH.

CLINICAL PHARMACOLOGY:

Tyzine® Nasal Solution (tetrahydrozoline hydrochloride), a sympathomimetic amine, possesses vasoconstrictor and decongestant actions when applied to nasal mucosa, resulting in vasoconstriction of the smaller arterioles of the nasal passages. Information on the absorption, distribution and elimination of the drug is not available.

INDICATIONS AND USAGE:

Tyzine® Nasal Solution is indicated for decongestion of nasal and nasopharyngeal mucosa.

CONTRAINDICATIONS:

Tyzine® Nasal Solution is contraindicated for patients who have shown previous hypersensitivity to its components. The 0.1% solution is contraindicated in children under six years of age. **Tyzine®** Nasal Solution is not to be used for infants under two years of age. **Tyzine®** Pediatric Nasal Drops (0.05%) should be used for children between the ages of 2 and 6 years (See "Dosage and Administration"). **Tyzine®** Nasal Solution should not be used by patients under treatment with Monoamine Oxidase (MAO) Inhibitors.

WARNINGS:

Overdose in children may produce profound

sedation. This may be accompanied by profuse sweating, hypotension or even shock (See "Overdosage").

General:

Avoid doses greater or more frequent than those recommended below. Excessive dosage in children may, on rare occasions, cause severe drowsiness. Profuse sweating may accompany this effect. Overdosage may also cause marked hypotension or even shock. Use cautiously in patients with cardiovascular disease (e.g., coronary artery disease, hypertension), and metabolic-endocrine diseases (e.g., hyperthyroidism, diabetes).

Information for Patients:

Patients should be advised to follow the prescribed dosage regimen. The spray should be administered with the head held upright. To spray, squeeze bottle quickly and firmly and sniff briskly. Instillation of the nose drops can be most conveniently accomplished with the patient in the lateral head-low position.

Drug Interactions:

DRUG	EFFECT
Monoamine Oxidase (MAO) Inhibitors	Hypertension

Pregnancy:

Pregnancy Category C. Animal reproduction studies have not been conducted with **Tyzine®**. It is also not known whether **Tyzine®** Nasal Solution can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Tyzine®** Nasal Solution should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

It is not known whether this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when **Tyzine®** Nasal Solution is administered to a nursing woman.

ADVERSE REACTIONS:

Local application of **Tyzine®** Nasal Solution can be

associated with burning, stinging, sneezing or dryness of the mucosa. Occasionally, systemic sympathomimetic effects can occur, including headaches, drowsiness, weakness, tremors, light-headedness, insomnia, and palpitations. Rebound congestion can also occur, and is characterized by chronic swelling of the nasal mucosa resulting in chronic redness, swelling and rhinitis. If adverse reactions occur, discontinue use.

OVERDOSAGE:

The administration or ingestion of overdoses of **Tyzine**[®] (tetrahydrozoline hydrochloride) Nasal Solution may result in oversedation in young children. Overdoses have caused hypertension, bradycardia, drowsiness and rebound hypotension in adults; a shock-like syndrome with hypotension and bradycardia may also occur. In either case, the treatment of overdose is usually that of watchful expectancy and general supportive measures. The patient should be kept warm, fluid balance should be maintained orally, if possible, and parenterally, if necessary.

If the respiratory rate drops to 10 or below, the patient should be given oxygen, and respiration assisted. Blood pressure should be watched carefully to prevent a hypotensive crisis.

There is no known antidote for **Tyzine**[®] Nasal Solution. The use of stimulants is contraindicated. To date, we have had no report of fatalities resulting from overdoses of **Tyzine**[®] Nasal Solution and while the symptoms resulting from **Tyzine**[®] Nasal Solution overdose may be alarming, they are self-limiting and the patient recovers with no sequelae.

DOSAGE AND ADMINISTRATION:

Adults and Children 6 Years and Over:

Tyzine[®] 0.1% Nasal Solution

It is recommended that 2 to 4 drops of **Tyzine**[®] 0.1% Nasal Solution be instilled in each nostril as needed, never more often than every three hours. Less frequent administration is usually sufficient since relief is maintained for four hours or longer in most cases, and often for as long as eight hours. Bedtime instillation usually assures sleep undisturbed by the need for remediation before morning, or by insomnia from central stimulation.

Tyzine[®] 0.1% Nasal Spray

It is recommended to squeeze quickly and firmly three or four times **Tyzine**[®] 0.1% Nasal Spray in each nostril as needed, never more often than every three hours.

Less frequent administration is usually sufficient since relief is maintained for four hours or longer in most cases, and often for as long as eight hours. Bedtime instillation usually assures sleep undisturbed by the need for remediation before morning, or by insomnia from central stimulation.

Children 2 to 6 Years of Age:

Tyzine[®] 0.05 % Pediatric Nasal Drops

Note: Do not use Tyzine[®] 0.1% Nasal Solution or **Tyzine**[®] 0.1% Nasal Spray

It is recommended that 2 to 3 drops of **Tyzine**[®] 0.05% Pediatric Nasal Drops be instilled in each nostril as needed, and never more often than every three hours. Relief usually lasts for several hours, so that instillation is usually needed only every four to six hours. Instillation of nose drops can be most conveniently accomplished with the patient in the lateral head-low position.

HOW SUPPLIED:

Tyzine[®] Nasal Solution (0.1%) is available in:

30 mL bottles - NDC 0482-4760-30

15 mL Nasal Spray Bottles- NDC 0482-4760-15

Tyzine[®] Pediatric Nasal Drops (0.05%) is available in:

15 mL bottles - NDC 0482-4770-15

Recommended Storage: Store below 86°F (30°C).

Rx Only

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Revised 4/99

IL062-R2

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