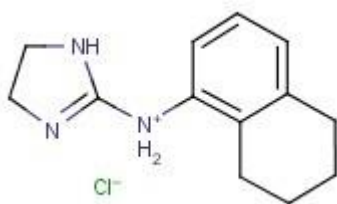


NAME OF THE MEDICINE

AUSTRALIAN APPROVED NAME

Tramazoline hydrochloride

CHEMICAL STRUCTURE



Molecular Formula: C₁₃H₁₈ClN₃

Molecular Weight: 251.7551g/mol

Chemical Name: Tramazoline hydrochloride

CAS REGISTRY NUMBER

3715-90-0

DESCRIPTION

Spray-Tish Menthol is a nasal spray for the local treatment of blocked and stuffy noses. It contains as the active ingredient, tramazoline hydrochloride in a strength of 1.18 mg/mL. Benzalkonium chloride is used as a preservative. Spray-Tish Menthol also contains menthol, cineole and camphor as aromatic agents.

Spray-Tish Menthol also contains citric acid monohydrate, sodium hydroxide, hypromellose, povidone, glycerol, magnesium sulfate, magnesium chloride, calcium chloride, sodium bicarbonate, sodium chloride and purified water.

PHARMACOLOGY

Tramazoline hydrochloride, an alpha-sympathomimetic, has a vasoconstricting effect and rapidly reduces swelling of the nasal mucosa. This leads to a rapid and long-lasting decongestion of the

nasal passages. After intranasal administration of Spray-Tish Menthol, local vasoconstriction usually occurs within 5 minutes and lasts for up to 8 hours.

INDICATIONS

For the symptomatic relief of nasal congestion associated with common cold, hayfever and rhinitis.

CONTRAINDICATIONS

Spray-Tish Menthol should not be used in:

- Patients with dry diseases of the nasal mucous membrane which form crusts and scabs (rhinitis sicca).
- Patients after cranial surgery via the nasal cavity.
- Patients with narrow-angle glaucoma.
- Patients with hypersensitivity to tramazoline hydrochloride, benzalkonium chloride or any other excipient in Spray-Tish Menthol.
- Children under six years of age, as specific studies to establish safety are not available.

PRECAUTIONS

Spray-Tish Menthol should be used with caution and on medical advice in patients with arterial hypertension, heart diseases, hyperthyroidism, diabetes mellitus, prostate hypertrophy, pheochromocytoma and porphyria due to the potential risk of systemic absorption.

Patients with hypertension, hyperthyroidism and glaucoma should consult their doctor before commencing treatment.

Caution should be used in patients receiving MAO inhibitors, tricyclic antidepressants, vasopressor drugs and antihypertensives (see Interactions with other Drugs).

The use of Spray-Tish Menthol for prolonged periods of time is not recommended. If the symptoms have not disappeared following the use of Spray-Tish Menthol for 3 days, a physician should be consulted as to whether the treatment should be continued or not.

Frequent or prolonged use may cause nasal congestion to recur or worsen. If congestion persists, a physician should be consulted.

Patients with chronic nasal stuffiness should consult their physician rather than continue the use of Spray-Tish Menthol. Prolonged use of mucous membrane-decreasing cold remedies may lead to chronic inflammation (and thus to a blocked nose) and finally to wasting (atrophy) of the nasal mucous membrane.

Rebound congestion (marked mucosal swelling) can occur on cessation of continuous treatment over long periods, after the therapeutic effect has abated.

Care should be taken that Spray-Tish Menthol does not enter the eyes as it may cause irritation.

Spray-Tish Menthol contains the preservative benzalkonium chloride which may cause irritation of the nasal mucosa.

USE IN PREGNANCY

Safety of tramazoline hydrochloride in pregnancy has not been established. Therefore, Spray-Tish Menthol should not be used in the first trimester of pregnancy. In the second and third trimesters of pregnancy, Spray-Tish Menthol should only be used in pregnant women under medical advice if the potential benefits to the mother outweigh the possible hazards to the fetus.

USE IN LACTATION

Safety during lactation has not been established. No specific studies are available to determine the excretion of the active ingredient, tramazoline hydrochloride, in human breast milk following nasal administration. Therefore, Spray-Tish Menthol should only be used under medical advice if the benefits of using Spray-Tish Menthol in nursing mothers outweigh the possible effects on the child.

INTERACTIONS WITH OTHER MEDICINES

If monoamine oxidase inhibitors (MAO inhibitors), tricyclic antidepressants or vasopressor drugs are given simultaneously, effects on the cardiovascular system can lead to an increase in blood pressure. Combined use with tricyclic antidepressants can also lead to arrhythmias. Interactions with antihypertensives, especially those whose action involves the sympathetic nervous system, can be complex and may result in various cardiovascular effects.

ADVERSE EFFECTS

The following side effects may occur with the use of Spray-Tish:

Nervous system disorders: Headache, somnolence, sedation, dizziness, dysgeusia.

Psychiatric disorders: Hallucinations, insomnia, restlessness.

Cardiac disorders: Palpitations, tachycardia, arrhythmias.

Respiratory, thoracic and mediastinal disorders: Rhinorrhea, epistaxis, nasal oedema, nasal discomfort, nasal dryness and sneezing.

Gastro-intestinal disorders: Nausea.

Immune system disorders: Hypersensitivity.

Skin and subcutaneous tissue disorders: Rash, pruritus, skin oedema*.

General disorders and administration site conditions: Mucosal oedema*, fatigue.

Investigations: Blood pressure increased

*as symptom of hypersensitivity

DOSAGE AND ADMINISTRATION

Adults and children six years of age and over:

The recommended dose is 1 to 2 sprays into each nostril up to 4 times a day as required. Administration should not be continued longer than 3 days without medical advice.

Directions for Use

Patients should be advised not to pierce the nozzle or attempt to enlarge the hole, as the existing hole is designed to deliver the correct dose of Spray-Tish Menthol.

To use:

1. Remove protective cap.
2. Before using the spray pump for the first time, rapidly depress the spray pump 5 to 7 times until an even spray mist is released. Spray-Tish Menthol is now primed and ready for use. With subsequent use, the spray pump is immediately functional. However, if used infrequently, it may require repriming.
3. Blow nose thoroughly before using Spray-Tish Menthol.
4. Insert the spray adaptor into the nostril and depress the spray pump while breathing in gently through the nose. Administer 1 to 2 sprays and then repeat in the other nostril.
5. Replace the protective cap after use.

It is recommended that the spray adaptor be cleaned after use.

OVERDOSAGE

For information on the management of overdose, contact the Poison Information Centre on 131126.

Symptoms:

An increase in blood pressure and tachycardia may, especially in children, be followed by a drop in blood pressure, subnormal temperatures, shock and reflex bradycardia.

As with other alpha-sympathomimetics, the clinical picture of an intoxication with Spray-Tish Menthol may be confusing, because phases of stimulation and depression of the CNS and cardiovascular system may alternate.

Especially in children, intoxications result in CNS effects with seizures and coma, bradycardia, respiratory depression. Symptoms of stimulation of the CNS are anxiety, agitation, hallucinations and seizures. Symptoms of depression of the CNS are decrease of body temperature, lethargy, somnolence and coma.

In addition, the following symptoms may occur: mydriasis, miosis, sweating, fever, pallor, cyanosis of the lips, cardiovascular dysfunction, including cardiac arrest, respiratory dysfunction, including (respiratory failure, and respiratory arrest) and psychological alterations.

Therapy:

In case of nasal overdosing, rinse out or clean the nose carefully at once. Symptomatic treatment may be required.

PRESENTATION AND STORAGE CONDITIONS

Spray-Tish Menthol is supplied in pump-activated, metered dose containers of 10 mL (120 metered doses) and 15 mL (180 metered doses), containing tramazoline hydrochloride 1.18 mg/mL. Each metered dose contains 82 micrograms of tramazoline hydrochloride. Store below 25°C.

NAME AND ADDRESS OF THE SPONSOR

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

POISON SCHEDULE OF THE MEDICINE

Schedule 2 (Pharmacy Only Medicine)

DATE OF FIRST INCLUSION IN THE ARTG

Text approved by the Therapeutic Goods Administration (TGA) 8 October 1998.

AUST R 71751

sprayishmenth-ccds0159-03-piv6-29aug17

DATE OF MOST RECENT AMENDMENT

29 August 2017