SPRAY-TISH® MENTHOL

For the relief of nasal congestion

DESCRIPTION

Proprietary Name: Spray-Tish Menthol
Approved Name: Tramazoline hydrochloride

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 prompt 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 nose.
- 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 under medical advice in patients with prostate hypertrophy and acquired or congenital porphyria.

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

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 7 days, a physician should be consulted as to whether the treatment should be continued or not.

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.

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

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 foetus.

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 Drugs

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.

ADVERSE REACTIONS

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

Nervous system disorders:
Headache, tiredness (somnolence, sedation), restlessness, insomnia, dizziness, taste disturbances

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Headache, tiredness (somnolence, sedation), restlessness, insomnia, dizziness, taste disturbances
Psychiatric disorders: 
Hallucinations (presumably with children)

Cardiac disorders: 
Palpitation, tachycardia, blood pressure increase, cardiac arrhythmias

Respiratory, thoracic and mediastinal disorders: 
Burning and dryness of nasal mucosa, rhinorrhea, epistaxis and sneezing. 
Rebound congestion (marked mucosal swelling) can occur on cessation of continuous treatment over long periods, after the therapeutic effect has abated.

Gastro-intestinal disorders: 
Nausea

Immune system disorders: 
Hypersensitivity reactions (rash, pruritus, oedema of skin and mucous membrane)

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 5 to 7 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.
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

In case of overdose, immediately contact the Poisons Information Centre (call 13 11 26) for advice.
**Symptoms:**

In analogy with other alpha-sympathomimetics, the following symptoms of overdose may be expected: tiredness, occasionally insomnia, dizziness and nausea. An increase in blood pressure and tachycardia may, especially in children, be followed by subnormal temperatures, shock and reflex bradycardia.

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 as well as an increase in blood pressure may be displaced by a drop in blood pressure. 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: nausea, mydriasis, miosis, sweating, fever, pallor, cyanosis of the lips, cardiovascular dysfunction (tachycardia, cardiac arrhythmias, bradycardia, cardiac arrest, hypertonia, shock-like drop in blood pressure), respiratory dysfunction (respiratory failure, respiratory arrest) and psychological alterations.

**Therapy:**

Rinse out or clean the nose carefully at once. Symptomatic treatment may be required.

**PRESENTATION**

Spray-Tish Menthol is supplied in pump-activated, metered dose containers of 10 mL (120 metered doses), containing tramazoline hydrochloride 1.18 mg/mL. Each metered dose contains 82 micrograms of tramazoline hydrochloride.

**POISONS SCHEDULE**

S2

**NAME AND ADDRESS OF SPONSOR**

Boehringer Ingelheim Pty Limited  
ABN 52 000 452 308  
78 Waterloo Road  
North Ryde NSW 2113

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