AUSTRALIAN PRODUCT INFORMATION – SPRAY-TISH (TRAMAZOLINE HYDROCHLORIDE) SPRAY SOLUTION

1 NAME OF THE MEDICINE

Tramazoline Hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Spray-Tish contains the active ingredient tramazoline hydrochloride in a strength of 1.18 mg/mL.

Benzalkonium chloride 0.182 mg/mL is used as a preservative.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Spray-Tish is a Nasal Mist.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

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

4.2 DOSE AND METHOD OF 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.

To use:

1. Remove protective cap.
2. Before using the spray pump for the first time, rapidly depress the spray pump until an even spray mist is released. Your Spray-Tish 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.
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.

4.3 CONTRAINDICATIONS

Spray-Tish 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.
- Children under six years of age, as specific studies to establish safety are not available.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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

Patients with 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 for prolonged periods of time is not recommended. If the symptoms have not disappeared following the use of Spray-Tish 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. 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 does not enter the eyes as it may cause irritation.

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

Use in the elderly

No data available

Paediatric use

Spray-Tish is contraindicated in children under six years of age, as specific studies to establish safety are not available.

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Monoamine oxidase inhibitors (MAO inhibitors), tricyclic antidepressants or vasopressor 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. Combined use with tricyclic antidepressants can also lead to arrhythmias.

Antihypertensives

Interactions with antihypertensives, especially those whose action involves the sympathetic nervous system, can be complex and may result in various cardiovascular effects.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

Safety of tramazoline hydrochloride in pregnancy has not been established. Therefore, Spray-Tish should not be used in the first trimester of pregnancy. In the second and third trimesters of pregnancy, Spray-Tish 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 should only be used under medical advice if the benefits of using Spray-Tish in nursing mothers outweigh the possible effects on the child.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE 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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

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 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, psychological alterations.

Therapy

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

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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, local vasoconstriction usually occurs within 5 minutes and lasts for up to 8 hours.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sorbitol solution 70% (non-crystallising)

Citric acid monohydrate

Dibasic sodium phosphate dihydrate

Sodium chloride

Benzalkonium chloride

Purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

10 mL metered nasal mist containing tramazoline hydrochloride 1.18mg/mL in an Amber glass vial, fitted with a metered pump and a polypropylene nasal adapter with a polyethylene protective cap.

Each metered dose contains 82 micrograms of tramazoline hydrochloride. Each bottle contains 120 metered doses.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Molecular Formula: C13H18ClN3

Molecular Weight: 251.7551g/mol

Chemical Name: Tramazoline hydrochloride

CAS number

3715-90-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 2 (Pharmacy Only Medicine)

8 SPONSOR

Sanofi Consumer Healthcare,
87 Yarraman Place, Virginia,
Qld 4014 Australia.
Toll-free: 1800 818 806
Email: medinfo.australia@sanofi.com

9 DATE OF FIRST APPROVAL

Text approved by the Therapeutic Goods Administration (TGA) on 21 August 1998

AUST R 42391

10 DATE OF REVISION

09 September 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
6.5	Introduction of 10 mL bottle
8	Update of sponsor details