SPRAY-TISH®

Active ingredient: tramazoline hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Spray-Tish. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Spray-Tish.

Where to find information in this leaflet:

- 1. Why am I using Spray-Tish?
- 2. What should I know before I use Spray-Tish?
- 3. What if I am taking other medicines?
- 4. How do I use Spray-Tish?
- 5. What should I know while using Spray-Tish?
- 6. Are there any side effects?
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1. Why am I using Spray-Tish?

Spray-Tish contains the active ingredient tramazoline hydrochloride. Spray-Tish is a nasal decongestant. It works by clearing a stuffy or blocked nose by shrinking the inflamed and swollen blood vessels in the lining of the nose. Spray-Tish is used to relieve a stuffy or blocked nose (nasal congestion) associated with the common cold, hayfever and rhinitis. A runny nose, nasal congestion, itching and sneezing, are typical symptoms of a condition known as rhinitis.

2. What should I know before I use Spray-Tish?

Warnings

Do not use Spray-Tish if:

- you are allergic to tramazoline hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- the lining of your nose is dry and has formed crusts or scabs. For example, a condition called "rhinitis sicca"
- you have had brain surgery via the nasal cavity
- you have an eye problem called "narrow-angle glaucoma"

Check with your doctor or pharmacist if you:

- have any other medical conditions, including those listed below:
 - arterial hypertension
 - heart disease
 - an enlarged prostate

- a rare condition called "porphyria" (a disorder of blood pigment metabolism)
- phaechromocytoma (a tumour on the adrenal gland near the kidney which gives rise to hypertension)
- an eye problem called "glaucoma"
- high blood pressure
- hyperthyroidism (an overactive thyroid gland)
- diabetes mellitus.
- take any medicines for any other condition

Only use Spray-Tish if it has been prescribed for you by a doctor or recommended by your pharmacist.

Never give it to someone else even if their symptoms seem to be the same as yours.

You should not use Spray-Tish if the packaging is torn or shows signs of tampering.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Spray-Tish should not be used in the first trimester of pregnancy. In the second and third trimesters of pregnancy, special care is recommended and the benefits of Spray-Tish must be assessed against any risks. Your doctor will discuss the risks and benefits of using Spray-Tish while you are pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Special care is recommended if you are breastfeeding.

Use in children

Children under six years of age should not use Spray-Tish.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Spray-Tish and affect how it works. These include:

- medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants
- medicines used to lower blood pressure
- medicines containing tramazoline hydrochloride
- other medicines for a stuffy or blocked nose

It is important to discuss this with your doctor or pharmacist because Spray-Tish may in the presence of some medicines, increase side effects including changes to the heart rate or other changes to the cardiovascular system. Before using Spray-Tish you should also tell your doctor or pharmacist when you last used Spray-Tish or other medicines for a stuffy or blocked nose.

This is important as long-term use of Spray-Tish or other medicines used to treat a blocked or stuffy nose, may cause a chronic stuffy or blocked nose and damage the lining of your nose.

A condition called 'rebound congestion', which causes a chronic stuffy or blocked nose may also occur. This condition may occur when you stop using Spray-Tish, if you have used it for a longer period of time than recommended.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Spray-Tish.

4. How do I use Spray-Tish?

How much to use

- The recommended dose for adults and children six years of age and over is 1 to 2 sprays into each nostril up to four times daily as required. If your doctor or pharmacist has changed this dose you should ask for further information from your doctor or pharmacist.
- Do not use Spray-Tish for more than 3 days without medical advice.
- Frequent or prolonged use may cause nasal congestion to recur or worsen.
- Follow the instructions provided with the medicine.

- If congestion persists, consult your doctor or pharmacist.
- Do not exceed the recommended dosage.

How to use Spray-Tish

Read complete directions carefully and use only as directed.

Do not spray in or around your eyes. It may cause irritation.

Do not pierce the nozzle or attempt to enlarge the hole. The hole in the nozzle is a special size to allow the correct dose of Spray-Tish to enter your nostril when you depress the spray pump.

- 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 (see Figure 1). Your Spray-Tish is now primed and ready for use.



(Figure 1)

With subsequent use, the spray pump is immediately functional. However, if used infrequently, it may require repriming.

3. Blow nose thoroughly before using the nasal spray.

4. Insert the spray adaptor into the nostril and depress the spray pump while breathing in gently through the nose (see Figure 2). Administer 1 to 2 sprays and then repeat in the other nostril.



(Figure 2)

5. Replace protective cap after use.

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

Ask your doctor or pharmacist for advice if you have any problems with using this medicine.

If you use too much Spray-Tish

If you think that you have used too much Spray-Tish, or if you have accidentally swallowed some or all of the contents, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Signs of overdose expected may include tiredness, occasionally insomnia, dizziness and nausea. An increase in blood pressure and heart rate may, especially in children, be followed by a fall in body temperature, drop in blood pressure, shock and slowing of the heart. In addition, other symptoms of overdose not mentioned above may also occur.

5. What should I know while using Spray-Tish?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Spray-Tish.

Things you should not do

- Spray-Tish is for short-term use only. Spray-Tish should not be used for more than 3 days at a time unless advised by a doctor or pharmacist.
- Do not use Spray-Tish when the medicine is running out and it is no longer possible to obtain a firm spray.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Spray-Tish affects you.

Spray-Tish may cause drowsiness, dizziness, fatigue or hallucinations in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Looking after your medicine

- It is recommended that the spray adaptor be cleaned after use.
- Store below 30°C.
- Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
 Nervous system-related headache dizziness drowsiness, sleepiness Psychiatric-related 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
 hallucinations insomnia restlessness Respiratory-related 	
 runny nose sneezing nasal dryness nasal discomfort swelling of the nose bleeding from the nose Gut-related 	
 nausea Immune-related hypersensitivity (shown by symptoms of fluid 	

Less serious side effects	What to do
retention under muscle or skin)	
General	
 changes to your sense of taste 	
 increase in blood pressure 	
 Spray-Tish contains the preservative benzalkonium chloride which may irritate the lining of your nose. 	

Serious side effects

Serious side effects	What to do
 Allergy-related: swelling of the face, lips, mouth, tongue skin rash, hives or itching Heart-related: 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
 change in heart rate fast or irregular heart beat 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Spray-Tish contains

Active ingredient (main ingredient)	Each spray contains 82 micrograms (µg) of tramazoline hydrochloride
Other ingredients (inactive ingredients)	 benzalkonium chloride as a preservative dibasic sodium phosphate dihydrate sodium chloride sorbitol solution 70%

(non-crystallising)
 citric acid monohydrate
 purified water

Do not take this medicine if you are allergic to any of these ingredients.

What Spray-Tish looks like

Spray-Tish is the brand name of your medicine. It is a clear, colourless solution in amber glass bottles. Each bottle contains 10 mL of solution which provides 120 metered doses.

Aust R 42391.

Who distributes Spray-Tish

Spray-Tish is made in Italy and supplied in Australia by:

Sanofi Consumer Healthcare,

87 Yarraman Place, Virginia,

Qld 4014 Australia.

Toll-free: 1800 818 806

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