

Spray-Tish®

Tramazoline hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Spray-Tish.

It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

Keep this information with your nasal spray.

You may need to read it again later.

If you have any concerns about this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with your medicine. You may need to read it again.

What Spray-Tish is used for

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 relieves 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.

Before you use Spray-Tish

When not to use Spray-Tish

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.

Do not use Spray-Tish if you are allergic to tramazoline hydrochloride or any of the other ingredients in Spray-Tish. These ingredients are listed in full at the end of this leaflet.

If you are uncertain as to whether you have these allergies you should raise those concerns with your doctor.

Do not use Spray-Tish if you have, or have had, any of the following conditions:

- the lining of your nose is dry and has formed crusts or scabs. For example, a condition called "rhinitis sicca"
- after brain surgery via the nasal cavity
- an eye problem called "narrow-angle glaucoma".

If you are uncertain as to whether you have or have had any of these conditions you should raise those concerns with your doctor.

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

You should never use Spray-Tish after the EXPIRY DATE on the bottle or carton.

If you use it after the expiry date has passed, it may not work as well.

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

Before you start to use Spray-Tish

Before using Spray-Tish, you must tell your doctor if you have, or have had, any of the following conditions:

- arterial hypertension
- heart disease
- an enlarged prostate
- a rare condition called "porphyria" (a disorder of blood pigment metabolism)
- phaeochromocytoma (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.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor. Before using Spray-Tish you must tell your doctor or pharmacist if you are taking or using any other medicines, obtained with or without a doctor's prescription.

In particular you should tell your doctor or pharmacist if you are taking or using:

- 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.

Spray-Tish contains the preservative benzalkonium chloride which may irritate the lining of your nose.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

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.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Special care is recommended if you are breastfeeding. 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 breastfeeding.

Children

Spray-Tish should not be used in children under 6 years of age.

Using Spray-Tish

How to use Spray-Tish

At the end of this leaflet you will find directions on how to use Spray-Tish. Ask your doctor or pharmacist for advice if you have any problems with using this medicine.

Never spray Spray-Tish in or around your eyes.

It may cause irritation.

Recommended Dose

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.

If congestion persists, consult your doctor or pharmacist.

Overdose

Seek medical advice if you have used more than the recommended or prescribed dose of Spray-Tish or if you have accidentally swallowed some or all of the contents of Spray-Tish. Immediately telephone your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia).

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.

While using Spray-Tish

Things you must do

Tell your doctor or pharmacist if you begin taking or using any other medicine while you are using Spray-Tish.

Things you must 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.

Ability to drive or operate machinery

Be careful driving or operating machinery until you know how Spray-Tish affects you. It 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.

Side effects

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of using this medicine.

Spray-Tish can cause the following side effects:

- headache
- drowsiness, sleepiness
- restlessness
- insomnia
- dizziness
- changes to your sense of taste
- hallucinations
- swelling of the nose
- nasal dryness
- nasal discomfort
- runny nose
- bleeding from the nose
- sneezing
- nausea
- change in heart rate
- fast or irregular heart beat
- increase in blood pressure.

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after using Spray-Tish, so that these may be properly treated.

Allergic reactions may also occur. Symptoms of an allergic reaction may include:

- skin rash, hives or itching
- swelling of the face, lips, mouth or tongue

Tell your doctor immediately if you have an allergic reaction. You may require urgent medical attention. In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after using Spray-Tish.

After using Spray-Tish

Care and cleaning

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

Storage

Spray-Tish should be kept in a cool, dry place where the temperature stays below 30°C.

Do not freeze.

Keep Spray-Tish where young children cannot reach it.

Disposal

If you will not be needing Spray-Tish anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What Spray-Tish is

Spray-Tish is the brand name of your medicine. It is a clear, colourless solution in amber glass bottles. Each bottle contains 15 mL of solution which provides 180 metered doses.

Spray-Tish is identified by an Australian Registration Number and this number appears on the pack (AUST R 42391). Spray-Tish is available from your local pharmacy without a prescription.

Ingredients

Each spray of Spray-Tish contains:

- 82 micrograms (μg) of tramazoline hydrochloride.

Other ingredients include:

- benzalkonium chloride as a preservative
- sodium phosphate-dibasic dihydrate
- sodium chloride
- sorbitol solution 70% (non-crystallising)
- citric acid monohydrate
- purified water.

Manufacturer

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

Date of preparation: 29 August 2017

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Spray-Tish®

Tramazoline hydrochloride

Directions For Use

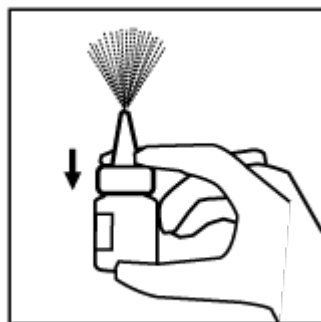
Read complete directions carefully and use only as directed.

Do not spray in or around your eyes.

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.

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

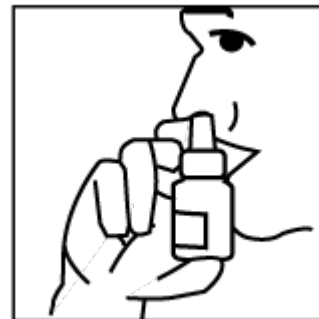


(Figure 1)

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.