

Spray-Tish[®] Menthol

Tramazoline hydrochloride

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Spray-Tish Menthol.

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 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 Menthol is used for

Spray-Tish Menthol is a nasal decongestant. It clears a stuffy or blocked nose by shrinking the inflamed and swollen blood vessels in the lining of the nose.

Spray-Tish Menthol relieves a stuffy or blocked nose (nasal congestion) associated with the common cold, hayfever and rhinitis. Typical symptoms of rhinitis include: nasal congestion, itching, sneezing and a runny nose.

Before you use Spray-Tish Menthol

When not to use Spray-Tish Menthol

Do not use Spray-Tish Menthol if you are allergic to tramazoline hydrochloride or any of the other ingredients in Spray-Tish Menthol. 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 or pharmacist.

Do not use Spray-Tish Menthol 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 or pharmacist.

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

You should never use Spray-Tish Menthol 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 Menthol if the packaging is torn or shows signs of tampering.

Before you start to use Spray-Tish Menthol

Before using Spray-Tish Menthol, you should 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 Menthol 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 Menthol 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 Menthol you should also tell your doctor or pharmacist when you last used Spray-Tish Menthol or other medicines for a stuffy or blocked nose.

This is important as long-term use of Spray-Tish Menthol 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 Menthol, if you have used it for a longer period of time than recommended.

Spray-Tish Menthol 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 Menthol 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 Menthol must be assessed

against any risks. Your doctor will discuss the risks and benefits of using Spray-Tish Menthol 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 Menthol must be assessed against any risks. Your doctor will discuss the risks and benefits of using Spray-Tish Menthol while you are breastfeeding.

Children

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

Using Spray-Tish Menthol

How to use Spray-Tish Menthol

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

Never spray Spray-Tish Menthol 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.

Ask your doctor or pharmacist for more information if you have been advised to use a different dose.

Do not use Spray-Tish Menthol 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 Menthol or if you have accidentally taken some or all of the contents of Spray-Tish Menthol.

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 Menthol

Things you must do

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

Things you must not do

Spray-Tish Menthol is for short-term use only. Spray-Tish Menthol should not be used for more than 3 days at a time unless advised by a doctor or pharmacist.

Do not use Spray-Tish Menthol when the medicine is running out and it is no longer possible to obtain a firm spray.

This is significant, as the correct dose of Spray-Tish Menthol may not enter your nostril when you depress the spray pump.

Ability to drive or operate machinery

Be careful driving or operating machinery until you know how Spray-Tish Menthol 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 Menthol 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
- 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 Menthol, 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 Menthol.

After using Spray-Tish Menthol

Care and cleaning

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

Storage

Spray-Tish Menthol should be kept in a cool, dry place where the temperature stays below 25°C.

Do not store in direct sunlight or heat. Do not freeze.

Keep Spray-Tish Menthol where young children cannot reach it.

Disposal

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

Product Description

What is Spray-Tish Menthol

Spray-Tish Menthol is the brand name of your medicine. It is a clear, faintly yellowish solution in amber glass bottles.

Spray-Tish Menthol contains menthol, cineole and camphor, which provide its fragrance.

Spray-Tish Menthol is available in bottles containing 10 mL of solution, which provides 120 metered doses, and in bottles containing 15 mL of solution, which provides 180 metered doses.

Spray-Tish Menthol is identified by an Australian Registration Number and this number appears on the pack (AUST R 71751).

Spray-Tish Menthol is available from your local pharmacy without a prescription.

Ingredients

Each spray of Spray-Tish Menthol contains

- 82 micrograms (g) of tramazoline hydrochloride.
- Other ingredients include:
- benzalkonium chloride as a preservative
- citric acid monohydrate
- sodium hydroxide
- hypromellose
- povidone
- glycerol
- magnesium sulfate
- magnesium chloride
- calcium chloride
- sodium bicarbonate
- sodium chloride
- menthol
- cineole
- camphor
- purified water.

Manufacturer

Spray-Tish Menthol 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

spraytishmenth-
ccds0159-03cmiv6-29aug17



(Figure 2)

5. Replace protective cap after use.

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

Spray-Tish® Menthol

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 Menthol 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 Menthol 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.