### SPRAY-TISH® MENTHOL

Active ingredient: tramazoline hydrochloride

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Spray-Tish Menthol. 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 Menthol.

#### Where to find information in this leaflet:

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

#### 1. Why am I using Spray-Tish Menthol?

**Spray-Tish Menthol contains the active ingredient tramazoline hydrochloride.** 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 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 Menthol?

#### Warnings

#### Do not use Spray-Tish Menthol 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 Menthol 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 Menthol 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 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.

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 Menthol.

#### 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 Menthol and affect how it works.

Medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants include:

- 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.

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 Menthol.

#### 4. How do I use Spray-Tish Menthol?

#### 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 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.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

#### How to use Spray-Tish Menthol

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.

1. Remove protective cap.

2. Before using the spray pump <u>for the first time</u>, 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.



(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 Menthol

If you think that you have used too much Spray-Tish Menthol, or if you have accidentally taken 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 Menthol?

#### Things you should do

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

#### Things you should 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.

#### Driving or using machines

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

Spray-Tish Menthol 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.

#### **Drinking alcohol**

Tell your doctor or pharmacist if you drink alcohol.

#### Looking after your medicine

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

- Store below 25°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
<ul> <li>Nervous system-related</li> <li>headache</li> <li>dizziness</li> <li>drowsiness, sleepiness</li> </ul>	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
<ul> <li>Psychiatric-related</li> <li>hallucinations</li> <li>insomnia</li> <li>restlessness</li> </ul>	
Respiratory-related	
<ul> <li>runny nose</li> <li>sneezing</li> <li>nasal dryness</li> <li>nasal discomfort</li> <li>swelling of the nose</li> <li>bleeding from the nose</li> </ul>	
Gut-related	
• nausea	
<ul> <li>Immune-related</li> <li>hypersensitivity (shown by symptoms of fluid</li> </ul>	

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

#### Serious side effects

Serious side effects	What to do
<ul> <li>Allergy-related:</li> <li>skin rash, hives or itching</li> <li>swelling of the face, lips, mouth, tongue</li> <li>Heart-related:</li> </ul>	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.
<ul> <li>change in heart rate</li> <li>fast or irregular heart beat</li> </ul>	

## 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 Menthol contains

Active ingredient (main ingredient)	82 micrograms (µg) of tramazoline hydrochloride
Other ingredients (inactive ingredients)	<ul> <li>benzalkonium chloride</li> <li>citric acid monohydrate</li> <li>sodium hydroxide</li> <li>hypromellose</li> <li>povidone</li> <li>glycerol</li> </ul>

<ul> <li>magnesium sulfate heptahydrate</li> </ul>
<ul> <li>magnesium chloride hexahydrate</li> </ul>
<ul> <li>calcium chloride dihydrate</li> </ul>
<ul> <li>sodium bicarbonate</li> </ul>
<ul> <li>sodium chloride</li> </ul>
<ul> <li>menthol</li> </ul>
• cineole
<ul> <li>camphor</li> </ul>
<ul> <li>purified water</li> </ul>

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

#### What Spray-Tish Menthol looks like

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.

AUST R 71751.

#### Who distributes Spray-Tish Menthol

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

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