## Telnasal Allergy Spray®

Active ingredient: Mometasone furoate monohydrate

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

This leaflet provides important information about using Telnasal Allergy Spray. 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 Telnasal Allergy Spray.

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

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

## 1. Why am I using Telnasal Allergy Spray?

Telnasal Allergy Spray contains the active ingredient mometasone furoate monohydrate. Telnasal Allergy Spray belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

Allergic Rhinitis (hayfever): Telnasal Allergy Spray is sprayed into the nose to help relieve symptoms that may occur with hayfever or other year round allergies, including stuffiness (congestion) in the nose, discharge, itching and sneezing. This medicine may also be used to help prevent these symptoms two to four weeks before the beginning of the pollen season.

There is no evidence that this medicine is addictive.

# 2. What should I know before I use Telnasal Allergy Spray?

#### Warnings

#### Do not use Telnasal Allergy Spray if:

- you are allergic to mometasone furoate monohydrate, or any of the ingredients listed at the end of this leaflet
- you have a tendency to bleed or recurrent nose bleeding
- you have severe nose infection, especially fungal infection
- you have had recent nose injury or nose surgery; you may wait until healing has occurred before using this medicine
- you have active or inactive tuberculous infections of the respiratory tract, bacterial, systemic viral infections or in herpes simplex.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering

Always check the ingredients to make sure you can use this medicine.

#### Check with your doctor or pharmacist if you:

- have any other medical conditions especially the following ones:
  - infection of the nose, sinus, mouth, throat, lungs or eye
  - o sores in the nose
  - recent injury or surgery to your nose
  - o open sores in your nose
- take any medicines for any other condition including CYP3A inhibitors (medicines for metabolic conditions) including cobicistat-containing products
- taking other corticosteroid medicines, either by mouth, as eye drops, as an asthma inhaler or by injection
- have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes
- have or recently suffered from any bacterial or viral infection, avoid coming into contact with anyone who has measles or chickenpox especially while you are using cortisone-type medicines. Tell your doctor if you do.

If you suddenly discontinue use of this medicine then reoccurrence of the underling condition, adrenocortical insufficiency or steroid withdrawal syndrome may occur. The risk may vary as per the potency of the steroid.

Typical signs and symptoms can be either systemic such as muscle or joint pain, tremors, weight loss and anxiety or nasal bleeding and nasal drip.

Following the use of intranasal corticosteroids, instances of increased eye pressure have occurred.

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</u>. Are there any side effects?

#### Pregnancy and breastfeeding

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

Your doctor or pharmacist will discuss the possible risks and benefits of using this medicine during pregnancy. Breastfeeding is not recommended during treatment with this medicine.

#### Use in Children

Do not use in children under 12 years of age.

It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed and discussed with your doctor or pharmacist.

## 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.

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

## 4. How do I use Telnasal Allergy Spray?

#### How much to use

Hayfever and allergies in adults (including the elderly) and children 12 years of age and older:

- Two sprays into each nostril once daily.
- It may take 1#2 days for full effect.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- Consult your pharmacist or doctor if symptoms are not relieved within 7 days.
- Once symptoms are controlled, reducing the dose to one spray in each nostril may be effective for maintenance.
- Do not use for more than 6 months without the advice of your pharmacist or doctor.
- Do not give to children under 12 years of age.

#### When to use Telnasal Allergy Spray

Telnasal Allergy Spray should be used once daily.

#### How to use Telnasal Allergy Spray

Your nasal spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use.

Do not pierce the nasal applicator.

If you are using the spray for the first time prime the pump by pumping the spray 10 times until a fine mist is produced.

If you have not used the pump for 14 days or more reprime by pumping 2 times.

- 1. Shake the bottle gently and remove the dust cap.
- 2. Gently blow your nose.
- 3. Close one nostril and put the nozzle into the other nostril.
- 4. Tilt your head forward slightly, keeping the bottle upright.
- Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
- Breathe out through your mouth. Repeat step 5 to inhale a second spray in the same nostril.
- 7. Remove the nozzle from this nostril and breathe out through the mouth.
- 8. Repeat steps 3 to 7 for the other nostril. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.

#### If you use too much Telnasal Allergy Spray

If you think that you have used too much Telnasal Allergy Spray, 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.

## 5. What should I know while using Telnasal Allergy Spray?

#### Things you should do

If you become pregnant while you are using this medicine tell your doctor or pharmacist.

Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

See your doctor immediately if you notice the symptoms of severe bacterial infection. These symptoms may include fever, persistent face/tooth pain on one side of the face, swelling around the eye area, or worsening of symptoms after an initial improvement.

#### How long to use it

You can stop taking Telnasal Allergy Spray when you obtain relief from the symptoms. It can be restarted if the symptoms reoccur.

See your doctor or pharmacist if your symptoms are not relieved within 7 days.

Do not use for more than 6 months without the advice of your pharmacist or doctor.

#### Things you should not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

#### If you forget to take it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to use your medicines as you would normally.

Do not use a double dose to make up for the dose you missed.

#### **Driving or using machines**

This medicine generally does not cause any problems with your ability to drive a car or operate machinery.

#### Drug testing for sport events:

This product is a corticosteroid for intranasal administration; it is not a restricted drug for sports.

Corticosteroid may be detected in blood and in the urine during drug testing; thus prior written permission for its use may be required by some sport agencies.

## Looking after your medicine

It is important to clean the nozzle regularly; otherwise, it may not work properly.

Remove the dust cap and gently pull off the nozzle. Wash the nozzle and dust cap in warm water and then rinse under a running tap. Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage

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the applicator and cause you not to get the right dose of medicine.

Allow the nozzle to dry. Push the nozzle back onto the bottle and replace the dust cap. The pump will need to be reprimed when first used after cleaning.

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

- Store below 25°C.
- Do not freeze.
- The bottle should be discarded after the labelled number of actuations or within 2 months of first use.

Store 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 or if the packaging is torn or shows signs of tampering.

## 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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  General  Sneezing  Nosebleeds or blood-tinged mucus  Sore throat or burning or irritation inside the nose after using this medicine. These symptoms are consistent with the use of corticosteroid nasal sprays.  Nasal ulceration  Nasal septum perforation  Throat irritation  Disturbances of taste and smell  Pharyngitis  Upper respiratory tract infection  Steroid withdrawal syndrome  Glaucoma  Increased intraocular pressure  Cataracts	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

#### More serious side effects

More serious side effects	What to do
Allergic-related     Rash, wheezing or breathlessness	Stop using the nasal spray, as you may be allergic to it.
	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.

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.

Long#term use of corticosteroid sprays may be associated with other side effects. Your doctor or pharmacist will monitor your health if you are using Telnasal Allergy Spray for extended periods of time.

#### 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 Telnasal Allergy Spray contains**

Active ingredient (main ingredient)	Mometasone furoate monohydrate
Other ingredients (inactive ingredients)	Microcrystalline cellulose, carmellose sodium, citric acid monohydrate, sodium citrate dihydrate, glycerol, polysorbate 80 and purified water  Preservatives: Benzalkonium chloride

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

#### What Telnasal Allergy Spray looks like

Telnasal Allergy Spray is a white to off- white suspension contained in HDPE bottles with a metered-dose, manual spray pump for intranasal administration. Available packs of 1 x 140 metered doses and in a twin pack of 2 x 140 metered doses.

Australian Registration Number: AUST R 330202

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## Who distributes Telnasal Allergy Spray

Sanofi Consumer Healthcare

87 Yarraman Place

Virginia, 4014, Australia

Freecall No: 1800 818 806

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