

# OMNARIS<sup>®</sup> Nasal Spray

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using OMNARIS?

OMNARIS contains the active ingredient ciclesonide, a corticosteroid. When sprayed into your nose, OMNARIS helps to stop hayfever (allergic rhinitis) symptoms that are due to pollen (seasonal allergic rhinitis) in people 6 years of age and older, or things in the environment such as house dust mites, pets such as cats or dogs, or moulds (perennial rhinitis) in people 12 years of age and older.

For more information, see Section [1. Why am I using OMNARIS?](#) in the full CMI.

### 2. What should I know before I use OMNARIS?

Do not use if you have ever had an allergic reaction to ciclesonide, other steroids or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions (e.g., immune compromised, not vaccinated for chickenpox or measles or have any type of infection), damage to or recent surgery on the nose, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Tell your doctor if you are switching from steroids that you take internally (e.g., by injection or by mouth), to OMNARIS.

For more information, see Section [2. What should I know before I use OMNARIS?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with OMNARIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use OMNARIS?

Use OMNARIS in each nostril, once every day, for as long as the doctor tells you. Do not suddenly stop using it.

More instructions can be found in Section [4. How do I use OMNARIS?](#) in the full CMI.

### 5. What should I know while using OMNARIS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using OMNARIS.</li><li>• Tell your doctor straight away if you feel unwell, have a reaction or experience any serious side effects during or after using ALVESCO (see Section 6. Are there any side effects?).</li><li>• Keep all your doctor's appointments so that your progress can be checked.</li></ul>
<b>Things you must not do</b>	<ul style="list-style-type: none"><li>• Do not suddenly stop using this medicine or change the amount you use without speaking to your doctor first.</li><li>• Do not use OMNARIS to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store the pack at room temperature, below 30°C. Do not freeze.</li><li>• Keep the spray in its foil pouch until you are ready to use it.</li></ul>

For more information, see Section [5. What should I know while using OMNARIS?](#) in the full CMI.

### 6. Are there any side effects?

Most side effects, if any, will be mild, and include headache, occasional nosebleed, stuffy, dry or painful nose or throat. Serious side effects that you need urgent attention for may be: frequent nosebleed, wheezing or problems breathing and serious allergic reactions (swollen nose, lips, face, eye or throat).

For more details about side effects, and what to do, see Section [6. Are there any side effects?](#) in the full CMI.

# OMNARIS<sup>®</sup> Nasal spray

Active ingredient: *ciclesonide*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using OMNARIS?](#)
- [2. What should I know before I use OMNARIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use OMNARIS?](#)
- [5. What should I know while using OMNARIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. WHY AM I USING OMNARIS?

OMNARIS contains the active ingredient **ciclesonide**. Ciclesonide is a corticosteroid which are used to reduce inflammation.

OMNARIS When sprayed into your nose helps to stop seasonal allergic rhinitis in people 6 years of age and older and perennial rhinitis in people 12 years of age and older.

Allergic Rhinitis (hayfever) may cause the inside of your nose to become inflamed or swollen, blocked, runny and itchy and you may sneeze.

You may have symptoms only during spring and summer (seasonal rhinitis) when it is caused by pollens from grasses or trees. Some people may experience symptoms all year round (perennial rhinitis). This is usually caused by house dust mites, pets or moulds.

## 2. What should I know before I use OMNARIS?

### Warnings

**Do not use OMNARIS if:**

- you are allergic to ciclesonide or any of the ingredients listed at the end of this leaflet
- you are under 6 years of age

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

**Check with your doctor if you:**

- have frequent nose bleeds
- have a nasal or sinus infection
- had a recent injury or surgery to your nose
- have ulcers or sores in your nose
- have any type of infection caused by bacteria, virus, fungus, or parasites

- have a history of tuberculosis (TB) infections
- have herpes simplex (virus) infection of the eye

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 [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

They will look at whether the benefits of having OMNARIS outweigh any possible effects on unborn or newborn babies.

## Having an operation

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

## 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 OMNARIS and affect how it works. These include:**

- other corticosteroid medicines such as tablets, asthma inhalers, nasal sprays, or eye/nose drops
- medicines that suppress the immune system (e.g., ciclosporin)
- some antifungal medicines (e.g., ketoconazole, itraconazole)
- some antiviral medicines (e.g., ritonavir, nelfinavir, cobicistat)
- some medicines for heart problems (such as diltiazem, verapamil)

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

## 4. How do I use OMNARIS?

### How much to use

- OMNARIS is for use in the nose only.
- Use two sprays in each nostril once a day.
- Do not use any more than this.
- Elderly people have the same dose as other adults.

Your doctor may change this dosage, depending on how you respond to this medicine, so that you use the lowest dose that controls your symptoms.

Follow the instructions provided and use OMNARIS until your doctor tells you to stop.

## How to use your OMNARIS inhaler

1. Remove OMNARIS from its foil pouch. Count 4 months from this date and write the date (that is 4 months from removing the bottle from the foil pouch) on the space provided on the nasal spray bottle. It is important to throw away the nasal spray bottle after this date.
2. Before you use OMNARIS for the first time, you will need to prime the bottle. Hold the bottle upright and shake the bottle gently. To prime OMNARIS Nasal Spray, fully press down on the finger rests of the applicator eight times (See Figure 1). If you do not use the nasal spray for 4 days, you will need to shake the bottle gently, and prime the pump again by spraying one time, or until you see a fine mist.

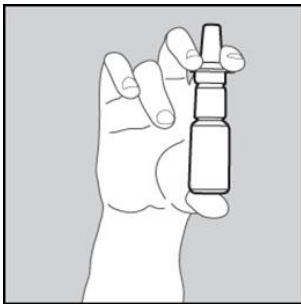


Figure 1

### Using the spray

1. Gently blow your nose to clear your nostrils if needed
2. Shake the bottle gently and remove the cap
3. Hold the bottle firmly with your index and middle finger on either side of the nozzle while supporting the base of the bottle with your thumb (Figure 1)
4. Insert the nozzle tip into one nostril, and close the other nostril with your finger (Figure 2)



Figure 2

5. Tilt your head forward slightly and keeping the bottle upright, press the pump quickly and firmly and inhale through your nose as you spray (Figure 3).

**Do not spray in eyes or directly onto the nasal septum (the wall between the two nostrils).**



Figure 3

6. Repeat steps 3-5 for the second spray in the same nostril and for each spray in the other nostril.

### How to clean it

After daily use of your nasal spray, wipe the nozzle tip with a clean tissue and replace the cap.

If the nozzle is clogged or requires more thorough cleaning, use the following cleaning instructions:

1. Remove the cap, grasp the white plastic pump firmly with one hand and then carefully pull upwards on the shoulders of the nozzle with the other hand to free the nozzle
2. Wash the cap and nozzle with warm water
3. Dry and replace the nozzle. The nozzle will snap into place when properly positioned
4. Prime the pump by spraying one time or until a fine mist appears
5. Replace the cap.

Do not try to unblock the tiny spray hole on the nozzle tip with a pin or other sharp object.

Do not twist or attempt to remove the white plastic pump attached to the medication bottle.

### How to know when your nasal spray bottle is empty

The amount of nasal spray left can be seen through a window on the bottle.

### If you forget to use OMNARIS

OMNARIS should be used regularly at the same time each day.

If you miss your dose at the usual time, have it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and have your next dose when you are meant to.

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

### If you use too much OMNARIS

If you think that you have used too much OMNARIS on one occasion, there is nothing to worry about.

If you use too much of it over a long time (months or years), you may start to get unwanted side effects inside your nose and body.

### 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 OMNARIS?

### Things you should do

**Call your doctor straight away if:**

- your nose starts to bleed or becomes infected, red, itchy or swollen
- you have any problems with your eyesight (i.e blurred vision). You may need to have your eyes checked by an eye specialist
- you have wheezing or other problems breathing
- you become pregnant while using OMNARIS

**Other things you should do:**

- keep all of your doctors appointments so that your progress can be checked. Your doctor may also change the dose if needed and check any effects on the nose and your general health.
- children and younger adults especially should see their doctor regularly so that they can be watched carefully for any effects on their growth.
- remind any doctor, dentist or pharmacist you visit that you are using OMNARIS

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not use OMNARIS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

**Do not change the amount you use without speaking to your doctor first.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how OMNARIS affects you.**

### Looking after your medicine

- Store the pack at room temperature, below 30°C. Do not freeze.
- Keep the spray in its foil pouch until you are ready to use it.

Follow the instructions above on how to look after 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 windowsills

**Keep it where young children cannot reach it.**

### When to discard your medicine

- If your doctor or pharmacist tells you to stop taking this medicine.

- If the expiry date has passed.
- Four months after you first open the pouch, or when you have used all of the doses, whichever is first.

### 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.

## 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 about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Digestive system</b></p> <ul style="list-style-type: none"> <li>• pain or discomfort after eating</li> </ul> <p><b>Eyes, nose, throat and mouth</b></p> <ul style="list-style-type: none"> <li>• nosebleed (occasional)</li> <li>• irritated, swollen, stuffy or dry nose</li> <li>• red, sore, swollen and/or irritated throat, with or without fever</li> <li>• pressure or pain behind the eyes/nose (sinusitis) or ears</li> <li>• dry mouth</li> <li>• unpleasant or unusual taste sensation</li> <li>• sore, yellowish, raised patches in the mouth (thrush)</li> <li>• hole in the cartilage dividing the inside of the nose (perforated septum)</li> </ul> <p><b>Eyes</b></p> <ul style="list-style-type: none"> <li>• blurred vision or problems seeing properly</li> </ul> <p><b>Muscles and bones</b></p> <ul style="list-style-type: none"> <li>• back pain</li> <li>• limited growth (children and adolescents, especially when using OMNARIS for a long time)</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>• headache</li> </ul> <p><b>Respiratory system</b></p> <ul style="list-style-type: none"> <li>• cough</li> <li>• feeling of congestion or fullness in the lungs</li> </ul> <p><b>Urinary tract</b></p> <ul style="list-style-type: none"> <li>• pain when urinating</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<b>Lungs</b> <ul style="list-style-type: none"><li>wheezing or other problems breathing</li></ul> <b>Nose</b> <ul style="list-style-type: none"><li>frequent nose bleeds</li></ul> <b>Hypersensitivity (allergic) reaction</b> <p>May include rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body.</p>	<b>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.</b>

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

Other side effects not listed may occur in some people.

**Always speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## Reporting side effects

After you have spoken to your doctor or pharmacist about any side effects you have, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What OMNARIS contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>ciclesonide</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>cellulose microcrystalline</li><li>carmellose sodium</li><li>hypromellose</li><li>disodium edetate</li><li>hydrochloric acid to adjust the pH</li><li>purified water and</li><li>nitrogen</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>potassium sorbate</li></ul>

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

OMNARIS does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

### What OMNARIS looks like

OMNARIS is a white to off-white milky liquid in a brown glass bottle with a pump. The bottle is sealed in a foil pouch.

There is also an oxygen-absorber sachet in the pouch that you should throw away after you open it.

Each spray gives you 50 micrograms ciclesonide.

There are two sizes:

- 10 mL bottle containing 60 sprays
- 15 mL bottle containing 120 sprays.

Not all pack sizes may be available.

ARTG Number: Aust R 167910.

### Who distributes OMNARIS

Chiesi Australia Pty Ltd  
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