

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

OMNAIR® Nasal Spray

50 micrograms (µg) in a volume of 70 microlitres (µl) per puff

Ciclesonide

Read all of this leaflet carefully before you start using OMNAIR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- **OMNAIR** Nasal spray has been prescribed for you personally and should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **OMNAIR** is and what it is used for
2. What you need to know before you use **OMNAIR**
3. How to use **OMNAIR**
4. Possible side effects
5. How to store **OMNAIR**
6. Contents of the pack and other information

1. What OMNAIR is and what it is used for

OMNAIR Nasal spray is a metered-dose, manual pump spray formulation containing a hypotonic aqueous suspension of ciclesonide.

OMNAIR belongs to a group of medicines called corticosteroids.

OMNAIR Nasal spray is used for the treatment of seasonal or all-year round allergy swelling and irritation in the nose, blocked or runny nose, sneezing and itchy nose.

2. What you need to know before you use Omnair

Do not use OMNAIR:

- if you are hypersensitive (allergic) to ciclesonide or any of the other ingredients of **OMNAIR** listed in section 6.
- active lung tuberculosis

Warnings and precautions

Tell your doctor or health care provider before using **OMNAIR**:

- if you had recent nasal septal ulcers, nasal surgery, or nasal trauma
- if you have active tuberculosis infections of the respiratory tract
- if you have untreated local or systemic fungal or bacterial infections, systemic viral (i.e. chickenpox or measles) or parasitic infections, or ocular herpes simplex because of potential for worsening of these infections
- if you have infections of the nose and throat with *Candida albicans*
- if you have blurred vision as nasal and inhaled corticosteroids may result in the development of glaucoma and/or cataracts if you have an underactive adrenal gland

Take special care with OMNAIR:

Children and adolescents: When using **OMNAIR** for a long time, this may cause children to grow more slowly. The doctor will check your child's height regularly and make sure your child is taking the lowest possible dose. **OMNAIR** is only indicated for use in children aged 6 years or older for seasonal allergy and adolescents aged 12 years or older for all-year round allergy.

Other medicines and OMNAIR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

OMNAIR Nasal spray appears to have no interaction with warfarin or salicylic acid. However, **OMNAIR** Nasal spray should be administered with caution when taking ketoconazole.

OMNAIR with food and drink and alcohol

There is no information available about the use of **OMNAIR** with food and drink and alcohol.

Pregnancy, breastfeeding and fertility

Pregnancy

There are no adequate and well-controlled studies with **OMNAIR** Nasal Spray in pregnant women.

Hypoadrenalism may occur in infants born from mothers receiving corticosteroids during pregnancy. Such infants should be carefully monitored.

Breast-feeding

Safety in breastfeeding has not been established. It is not known if ciclesonide is excreted in human milk. However, other corticosteroids are excreted in human milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent **OMNAIR** may interfere your daily activities. You should ensure that they do not engage in the above activities until you are aware of the measure to which OMNAIR® affects you.

3. How to use OMNAIR

Do not share medicines prescribed for you with any other person.

Always use **OMNAIR** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor may adjust your dose so that you are taking the lowest dose that will control your symptoms.

You may notice an improvement in your symptoms after one day.

The usual dose of **OMNAIR** Nasal spray for seasonal allergy symptoms in adults and children (6 years of age and older) is 2 sprays in each nostril once daily. You should not use more than a total of 2 sprays in each nostril daily.

The usual dose of **OMNAIR** Nasal spray for all year-round allergy symptoms in adults and children (12 years of age and older) is 2 sprays in each nostril once daily. You should not use more than a total of 2 sprays in each nostril daily.

Preparing for use

- Remove **OMNAIR** Nasal spray from its foil pouch. Count 4 months from this date and write this date (that is 4 months from removing the bottle from the foil pouch) on the sticker provided on the carton. Peel off this sticker and place it in the space provided on the nasal spray bottle. It's important to throw away the nasal spray bottle after this date.

- Prior to initial use, **OMNAIR** Nasal spray must be gently shaken and then the pump must be primed by actuating eight times. If the product is not used for four consecutive days, it should be gently shaken and re-primed with one spray or until a fine mist appears.

Precautions for use

Shake gently before use. Do not spray in eyes.

Handle glass bottle with care, do not use if pouch or bottle is damaged or broken

Using the Spray

1. Blow the nose to clear nostrils if needed.
2. Shake the bottle gently and remove the dust cap.
3. Hold the bottle firmly with index and middle finger on either side of the spray tip while supporting the base of the bottle with the thumb (**Figure 1**).



Figure 1

4. Insert spray tip into one nostril and close the other nostril with a finger. (**Figure 2**).



Figure 2

5. Tilt the head forward slightly and keeping the bottle upright, press the pump quickly and firmly and inhale through the nose while spraying (**Figure 3**). Avoid spraying 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.
7. Repeat steps 1-6 in the other nostril.

If you use more OMNAIR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use OMNAIR:

If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten doses.

4. Possible side effects

OMNAIR Nasal spray can have side effects.

Not all side effects reported for **OMNAIR** are included in this leaflet. Should your general health worsen while using **OMNAIR**, please consult your doctor, pharmacist or other healthcare professional for advice.

Common side effects

- Cough, inflammation of the mouth and throat, nosebleed, sinusitis
- Headache, nasal passage irritation, throat & voice box pain
- Upper respiratory tract infection, influenza (flu)
- Vomiting

Uncommon side effects

- Nasal dryness, throat & voice box pain, runny nose, nasal septum disorder, throat irritation
- Unpleasant taste in the mouth
- Candidiasis, inflammation of the nasal passages
- Dry mouth, indigestion

Reporting of suspected adverse reactions

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to Acino Pharma via email to drugsafety_ZA@arceralifesciences.com or to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **OMNAIR**.

5. How to store OMNAIR

Store all medicines out of reach of children.

Store below 25 °C.

Do not freeze. Do not refrigerate. SHAKE CONTAINER GENTLY BEFORE USE.

Do not use after the expiry date stated on the container. Do not use **OMNAIR** 4 months after opening foil pouch.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OMNAIR contains:

The active substance is ciclesonide.

The other ingredients are microcrystalline cellulose, carboxymethylcellulose sodium, hydroxypropyl methylcellulose, potassium sorbate, disodium edetate; and hydrochloric acid to adjust the pH to 4,5.

What OMNAIR looks like and contents of the pack

OMNAIR Nasal spray, 50 µg (60 or 120 puff metered spray): An amber glass bottle containing a white to off-white suspension.

OMNAIR® Nasal spray is supplied in an amber glass bottle covered with a plastic sleeve, with a snapped-on white, plastic metered- pump, packed together in an aluminium foil pouch. The glass bottle is available as a 10 ml bottle (60 puffs/bottle) and a 15 ml bottle (120 puffs/bottle).

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

South Africa

Tel. 087 742 1860

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