

PART III: CONSUMER INFORMATION

OMNARIS[®]

ciclesonide nasal spray

This leaflet is part III of a three-part "Product Monograph" published when OMNARIS was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OMNARIS. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

OMNARIS is a corticosteroid for use in adults and adolescents 12 years of age or older, to relieve the symptoms that may occur with hay fever [seasonal allergic rhinitis (SAR)] or other year-round allergies [perennial allergic rhinitis (PAR)], including stuffiness/congestion in the nose, runny nose, itching and sneezing.

What it does:

OMNARIS is a medication that is used in the nose. When taken according to the directions, OMNARIS can help relieve nasal congestion (blocked nose), runny nose, itching and sneezing. It reduces inflammation in the lining of the nose and nasal passages.

The therapeutic effects of corticosteroids like OMNARIS are not immediate. It may take a few days for this medicine to work. It is very important that you use it regularly. Do not stop treatment even if you feel better unless told to do so by your doctor.

When it should not be used:

Do not use this medication if:

- you are allergic to any of the ingredients in OMNARIS;
- you have an untreated infection of the nose (i.e. yellow or green discharge from the nose);
- your nose was recently operated on or injured. You may be told to wait until healing has occurred before using OMNARIS.

What the medicinal ingredient is:

Ciclesonide

What the important nonmedicinal ingredients are:

OMNARIS contains disodium edetate, hydrochloric acid, hydroxypropylmethylcellulose, microcrystalline cellulose and carboxymethylcellulose sodium, potassium sorbate and purified water.

What dosage forms it comes in:

OMNARIS comes in a bottle with a manual metered pump. Each spray activation delivers 50 micrograms of OMNARIS in a metered dose.

WARNINGS AND PRECAUTIONS

BEFORE you use OMNARIS talk to your doctor or pharmacist:

- About all health problems you have now or have had in the past;
- About all the medicines you take, including those you can buy without a prescription;
- If you ever had to stop taking other medicines for hay fever or other allergies because you were allergic to them or experienced other problems;
- If you have a history of tuberculosis (TB) infections;
- If you have sores in the nose;
- If you have an infection (fungal, bacterial, or viral);
- If you have herpes simplex (virus) infection of the eye;
- If you are taking other steroid medicine by mouth or by inhalation (breathing in);
- If you are taking drugs that suppress the immune system;
- If you are pregnant, plan to become pregnant or are breastfeeding. Do not use this medication during pregnancy or breastfeeding without first discussing it with your doctor.

INTERACTIONS WITH THIS MEDICATION

Talk to your doctor or pharmacist if you are taking ketoconazole, itraconazole, ritonavir, or nelfinavir. These drugs may interact with OMNARIS.

PROPER USE OF THIS MEDICATION

Your doctor will decide what an appropriate dosage of OMNARIS is for you.

Your doctor or pharmacist has explained when and how to take OMNARIS. Follow your doctor or pharmacist's directions carefully – they may be different from the information provided in this leaflet.

OMNARIS should be taken once daily.

Usual dose:

Adults and Adolescents (12 Years and Older): The recommended dosage is 2 sprays in each nostril once daily (total daily dose, 200 micrograms).

The maximum total daily dosage should not exceed 2 sprays in each nostril (200 micrograms/day).

OMNARIS is not presently approved for use in patients younger than 12 years of age.

How to Use OMNARIS Properly:

Preparing For Use:

1. Remove OMNARIS from its tamper proof foil pouch and write the date of opening on the sticker provided. Peel off this sticker and place it on your nasal spray bottle. It's important to throw away the nasal spray bottle 4 months after this date.
2. Shake the bottle gently and prime the pump by pressing downward on the shoulders of the applicator eight times. Read the complete instructions carefully and use only as directed. If unused within 4 or more consecutive days, reprime by spraying one time or until a fine mist appears. There is enough medication in this bottle to allow for the required priming and repriming, in addition to the 120 doses.

Using the Spray:

1. 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 spray tip while supporting the base of the bottle with your thumb (Figure 1).



Figure 1

4. Insert spray 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). **Avoid spraying in eyes or directly onto the nasal septum.**



Figure 3

6. If a second spray is required in this nostril, repeat steps 3-5. Repeat steps 3-6 for the other nostril.

Applicator Cleaning Instructions:

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

On a weekly basis or if the nasal applicator is clogged at any time, use the following cleaning instructions (**Do not try to unblock the tiny spray hole on the nasal applicator with a pin or other sharp object:**

1. Remove the cap and then gently pull upwards to free the nasal applicator.
2. Wash the cap and applicator with warm water.
3. Dry and replace the nasal applicator.
4. Prime the unit with one spray or until a fine mist appears.
5. Replace the cap.

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. You should discard the bottle after using 120 sprays or 4 months after opening the foil pouch, whichever comes first.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

It is very important that OMNARIS is used regularly. If a dose is missed, the next dose should be taken when it is due. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, OMNARIS may cause side effects in some people. Side effects that may occur with the use of corticosteroid nasal sprays, including OMNARIS, are:

- headache;
- nose bleeds;
- nasal ulcers;
- pain, burning, irritation, or dryness inside of the nose;
- nausea;
- dry mouth;
- decreased taste sensitivity;
- sore throat.

If any of these affects you severely, tell your doctor, nurse, or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical assistance
		Only if severe	In all cases	
Rare	Allergic Reactions: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			X
	Fungal infection in the nose.		X	

This is not a complete list of side effects. For any unexpected effects while taking OMNARIS, contact your doctor or pharmacist.

HOW TO STORE IT

Store at controlled room temperature (15–30°C). Do not freeze. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Questions or concerns: 1-800-668-6000.

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