

IMPORTANT: PLEASE READ

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 differ-