



## Patient Information Sheet

### Ciclesonide (marketed as Omnaris)

This is a summary of the most important information about Omnaris. For details, talk to your healthcare professional.

#### What Is Omnaris?

Omnaris is a corticosteroid nose spray which helps relieve inflammation. Omnaris is used for the treatment of nose symptoms (runny nose, itchy, and stuffy nose) associated with seasonal and year-round nasal allergy symptoms in adults and teens 12 years of age and older.

Omnaris was studied in children below 12 years of age, but did not relieve nose symptoms in study patients.

#### Who Should Not Use Omnaris?

You should not use Omnaris if you are allergic to anything in Omnaris.

#### What Are The Risks?

*The following are the major potential risks and side effects of Omnaris therapy. However, this list is not complete.*

- **Adrenal insufficiency or corticosteroid withdrawal.** When a patient has been taking a corticosteroid medicine by mouth for a long time and switched to Omnaris, the adrenal gland may not be able to make enough corticosteroid. Tell your healthcare professional if you get joint or muscle pain, weakness or depression.
- **Infection.** Omnaris may weaken the immune system giving you a higher chance for infections. Infections such as chicken pox or measles may be more serious and may even lead to death in some patients. Avoid exposure to infections and tell your healthcare professional if you have been exposed to or get an infection.
- **Slowed growth.** Omnaris may cause slowed growth in children. A child's growth should be monitored while using Omnaris.
- **Infection in the nose and pharynx** requiring treatment may occur if Omnaris is used for several months or longer. Omnaris may have to be stopped and the infection treated.
- **The most common side effect** that may occur with Omnaris is headache.

**What Should I Tell My Healthcare Professional?**  
**Before you start using Omnaris,** tell your healthcare professional if you:

- have recently had an ulcer, surgery, or trauma to your nose. Omnaris may delay wound healing.
- have or had tuberculosis
- currently have any type of infection
- have herpes affecting the eye
- have recently been taking a corticosteroid medicine by mouth
- have or had glaucoma or cataracts
- are trying to become pregnant, are already pregnant, or are breast-feeding

#### Can Other Medicines Or Food Affect Omnaris?

Omnaris and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare professional if you take ketoconazole.

#### How Should I use Omnaris?

- Use Omnaris exactly as prescribed. The recommended dose is 2 sprays in each nostril each day. Do not use more than a total of 2 sprays in each nostril a day. Omnaris must be used every day as prescribed to work for you.
- Read and follow the patient instructions carefully that come with Omnaris. Ask your healthcare professional to show you how to use the nose spray, and practice using it in front of them.
- Make sure you spray Omnaris up your nostrils and not against the side of your nostrils. **Do not spray Omnaris in your eyes.**
- Contact your healthcare professional if symptoms:
  - do not improve in 1 to 2 weeks for seasonal allergy symptoms
  - do not improve in 5 weeks for year-round nasal allergy symptoms
  - worsen

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