

OMNARIS

Ciclesonide Nasal Spray, 50mcg
120 puffs

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What Omnaris is used for

This medicine is used to treat nasal symptoms (i.e., runny nose, itchy nose, sneezing, and nasal congestion) that happen with:

- Seasonal nasal allergy in adults and adolescents 12 years of age and older.
- Year-round nasal allergy symptoms in adults and adolescents 12 years of age.

How Omnaris works

Omnaris Nasal Spray contains a medicine called ciclesonide, which is a synthetic corticosteroid (a substance that reduces inflammation).

Before you use Omnaris

- When you must not use it

Do not take this medicine if:

- you are allergic to ciclesonide or any other ingredients of this medicine (listed in Product Description)

- Before you start to use it

Before you take Omnaris, tell your doctor if you:

- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Omnaris passes into your breast milk. You and your doctor should decide if you will take Omnaris or breastfeed. You should not do both without first talking with your doctor.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements.

In particular, tell your doctor or pharmacist about the following medicines:

- Medicines to treat fungal infections, such as ketoconazole and itraconazole
- medicines for HIV such as ritonavir nelfinavir or cobicistat-containing products

These medicines may affect or may be affected by the treatment with Omnaris. They may also increase the effects of Omnaris and your doctor may wish to monitor you carefully if you are taking them.

Ask your doctor if you are not sure if you are taking a medicine listed above.

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

How to use Omnaris

- How much to use

- Use Omnaris exactly as prescribed by your doctor.
- Seasonal allergy symptoms may improve over 1 to 2 weeks; year-round allergy symptoms may improve over 5 weeks. If your symptoms do not improve or get worse, call your doctor.
- Omnaris is used 1 time each day, 2 sprays in each nostril. Do not use more than a total of 2 sprays in each nostril each day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you or someone else accidentally uses too much Omnaris on one occasion, there is nothing to worry about. However, 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.

Discuss any worries you may have about this with your doctor or pharmacist.

While you are using Omnaris

- Things you must do

Use your medicine exactly as your doctor has told you.

- Things you must not do

Do not give Omnaris to anyone else, even if they have the same symptoms or condition as you. It may harm them.

- Things to be careful of

For Intranasal Use only. Avoid spraying in eyes or directly onto the nasal septum (the wall between the two nostrils).

Omnaris is supplied in an amber glass bottle. Handle glass bottle with care. Do not use if pouch or bottle is damaged or broken.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet.

This Patient Information Leaflet summarizes the most important information about Omnaris. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about

Omnaris that is written for health professionals.

Side effects

Common side effects with Omnaris Nasal Spray include:

- Headache
- Nose bleeds
- Stuffy nose
- Ear pain
- Sore throat

Other risks of using Omnaris include:

- Nasal fungal infection
- Slow healing of wounds. Do not use Omnaris Nasal Spray until your nose has healed if: you have a sore in your nose, you have had surgery on your nose, or your nose has been injured.
- Eye problems, including glaucoma and cataracts. You should have regular eye exams.
- Immune system effects may increase your risk of infection. You should avoid being around people with Chicken Pox or Measles.
- Slow growth in children. A child taking Omnaris Nasal Spray should have his/ her growth checked regularly.

These are not all the possible side effects of Omnaris. Tell your doctor if you have any side effects that bother you or that does not go away. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Omnaris

- Storage

- Store Omnaris below 30°C.
- Do not freeze.
- Keep nasal spray clean and dry at all times.
- **Keep Omnaris and all medicines out of the reach of children.**

- Disposal

The amount of nasal spray left can be seen through a window on the bottle. Do not use this bottle for more than the labeled number of sprays or after the “discard by date” you wrote on the sticker when you opened the foil pouch. You may want to obtain a refill before your supply runs out if recommended by your doctor.

Product Description

- Ingredients

- Active ingredient
 - Ciclesonide
- Inactive ingredients
 - Microcrystalline cellulose
 - Carboxymethylcellulose sodium
 - Hypromellose
 - Potassium sorbate
 - Edetate disodium adjusted to a target pH of 4.5 with hydrochloric acid

- MAL number

MAL20102029ACRZ

Manufacturer

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Product Registration Holder

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