

OMNARIS[®]

(ciclesonide) Nasal Spray, 50 mcg

FOR INTRANASAL ADMINISTRATION ONLY

Please read this leaflet carefully before taking OMNARIS Nasal Spray. This leaflet does not contain the complete information about this medication. If you have any questions about OMNARIS Nasal Spray, ask your health care provider or pharmacist.

What you should know about OMNARIS Nasal Spray.

Your health care provider has prescribed OMNARIS Nasal Spray. It contains a medicine called ciclesonide, which helps relieve inflammation. This medication is used for the treatment of nasal symptoms associated with seasonal nasal allergy in adults and children 6 years of age and older and year-round nasal allergy in adults and adolescents 12 years of age and older.

The nasal spray delivers your medication as an aqueous spray. Once you begin treatment, use your nasal spray once a day, every day, as prescribed by your health care provider. OMNARIS Nasal Spray may begin to work within 24 hours after the first dose. Further symptom improvements may occur over 1 to 2 weeks for seasonal allergy symptoms and 5 weeks for year-round allergy symptoms. If your symptoms do not improve in that time frame or if your condition worsens, contact your health care provider.

Dosage

For Adults and Children (6 Years of Age and Older) with seasonal allergy symptoms: The recommended dose is **2 sprays in each nostril once daily.**

For Adults and Adolescents (12 Years of Age and Older) with year-round allergy symptoms: The recommended dose 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

1. Remove OMNARIS 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 your nasal spray bottle. It's important to throw away the nasal spray bottle after this date.
2. Before the first use, 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 you have not used the nasal spray for 4 days, shake the bottle gently and prime the pump again by spraying one time or until a fine mist appears.

Using the Spray

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

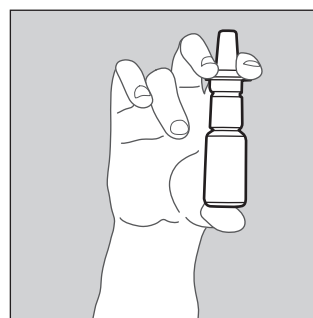


Figure 1

4. Insert applicator 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 (the wall between the two nostrils).**



Figure 3

- Repeat steps 3-5 for the second spray in the same nostril and for each spray in the other nostril.

Storage Instructions

Keep your nasal spray clean and dry at all times. Store medication between 59° and 86° F. Do not freeze. Keep out of the reach of young children.

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. 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 health care provider.

Applicator Cleaning Instructions

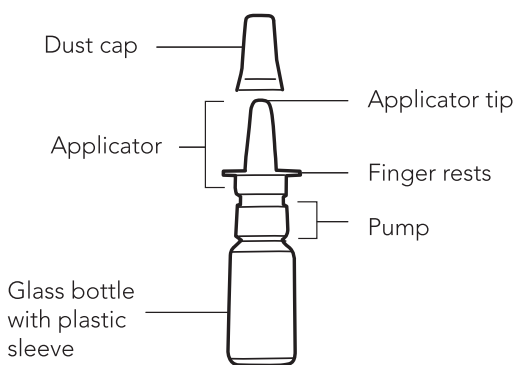


Figure 4

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

If the applicator is clogged or requires more thorough cleaning, use the following cleaning instructions (**Do not try to unblock the tiny spray hole on the applicator with a pin or other sharp object. Do not twist or attempt to remove the white plastic pump attached to the medication bottle.:**)

1. Remove the dust cap, grasp the white plastic pump firmly with one hand and then carefully pull upwards on the applicator finger rests with the other hand to free the applicator.

2. Wash the dust cap and applicator with warm water.
3. Dry and replace the applicator. The applicator will snap into place when properly positioned.
4. Prime the unit with one spray or until a fine mist appears.
5. Replace the dust cap.

Further Information

OMNARIS is supplied in an amber glass bottle in a protective plastic sleeve and should be handled with care.

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

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about something, then you should ask your doctor or pharmacist.

You may want to read this leaflet again. Please **DO NOT THROW IT AWAY** until you have finished your medicine.



Manufactured for:

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Marlborough, MA 01752 USA
Made in Germany

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For customer service, call 1-888-394-7377
To report adverse events, call 1-877-737-7226
For medical information, call 1-800-739-0565

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