



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Omnaris™

Common Name: Ciclesonide

PDL Category: Antiasthmatic – Nasal Steroids

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Veramyst™ (Fluticasone Furoate)	Preferred
Nasonex® (Mometasone Furoate)	Preferred
Fluticasone Propionate	Preferred

Summary

Indications and Usage: Treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older.

Mechanism of Action: The exact mechanism of corticosteroids is not known. Following hydrolysis, ciclesonide is converted to an active metabolite, des-ciclesonide, that has anti-inflammatory and inhibitory activities against various mediators (histamine, eicosanoids, leukotrienes, and cytokines) and cell types (mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) involved in allergic inflammation.

Dosage Forms: Nasal spray, 50mcg per spray, 120 sprays per bottle.

Recommended Dosage: 200mcg per day administered as 2 sprays (50mcg/spray) in each nostril once daily.

Common Adverse Drug Reactions: Headache, epistaxis, and nasal discomfort.

Contraindications: Hypersensitivity to any component of the product.

Manufacturer: Sepracor

Analysis: Omnaris™ is a nasal steroid that has shown to be effective in clinical trials at relieving seasonal and perennial allergic rhinitis when compared to placebo. Greater reflective and instantaneous improvements in total nasal symptom scores were reported by seasonal and perennial allergic rhinitis patients when compared to the placebo control group. A two week dose-ranging trial that evaluated efficacy of four doses of Omnaris™ (25 mcg, 50 mcg, 100 mcg, 200 mcg) with seasonal allergic rhinitis found that the Omnaris™ 200 mcg once daily dose was statistically significantly different from placebo, but the lower doses were not statistically significantly different from placebo. Efficacy of Omnaris™ has not been established in children below 12 years of age. Omnaris™ has not yet been comparatively studied with other available nasal steroids. Other preferred intranasal steroids exist on the Preferred Drug List that effectively treat nasal allergy symptoms for patients 2 years of age and older and are more cost effective than Omnaris™. Therefore, it is recommended Omnaris™ be added to the Preferred Drug List as a Non-Preferred Drug.

IME Recommendation:

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| <input type="checkbox"/> Preferred Drug | <input type="checkbox"/> Recommended Drug |
| <input checked="" type="checkbox"/> Non-Preferred Drug | <input type="checkbox"/> Non-Recommended Drug |
| <input type="checkbox"/> Preferred Drug with Conditions | |