



Therapeutic Class ReviewSM

Nasal – Ciclesonide (OmnarisTM) & olopatadine (Patanase[®])

October 2008

New Product for Review:

ciclesonide (OmnarisTM)[Sepracor]

olopatadine (Patanase[®])[Alcon]

Dossier Provided by Manufacturer: Yes

Dossier Evaluation: 3

Dossier Evaluation: 2

1 - Dossier missing significant clinical trial(s).

2 - Mfg. provided all relevant trials; Missing pharmacoeconomic model.

3 - Mfg. provided all relevant trials and information.

Executive Summary

- Ciclesonide (Omnaris) is an intranasal corticosteroid indicated for the treatment of the symptoms of:
 - Seasonal allergic rhinitis (SAR) in patients 6 years of age and older.
 - Perennial allergic rhinitis (PAR) in patients 12 years of age and older.
- Olopatadine (Patanase) is an intranasal antihistamine indicated for the treatment of the symptoms of SAR in patients 12 years of age and older.
- Ciclesonide (Omnaris) was approved by the FDA on October 20, 2006.
- Olopatadine (Patanase) was approved by the FDA on April 15, 2008.
- In the U.S., allergic rhinitis affects up to 40 million people annually.
- Compared to antihistamines, nasal corticosteroids provide the best overall relief of sneezing, runny nose, nasal congestion, and itching. ^[33]
- Nasal corticosteroids are considered first-line treatment for moderate-to-severe allergic rhinitis. ^[33]
- Treatment guidelines recommend intranasal corticosteroids as first-line therapy for moderate-to-severe PAR. ^[31]
- Nasal antihistamines are useful for providing a quick onset and relief of symptoms, but they must be used multiple times per day and only work on nasal symptoms.
- Oral and nasal antihistamines are first-line for mild-to-moderate intermittent or mild persistent rhinitis. ^[33]
- Ciclesonide (Omnaris) is more expensive than generically available inhaled nasal steroids.

- Ciclesonide (Omnaris) expires four months after it is removed from its foil pouch.
- There are no comparative trials with other allergic rhinitis medications for either ciclesonide (Omnaris) or olopatadine (Patanase).

Evidence

- The evidence for ciclesonide (Omnaris) is of uncertain validity. Available evidence includes:
 - Three studies in patients with SAR.
 - Four studies in patients with PAR.
- There is no evidence demonstrating the superiority of ciclesonide (Omnaris) over other intranasal corticosteroids in the treatment of SAR or PAR.
- There is no direct evidence of differences in harms between ciclesonide (Omnaris) and other intranasal corticosteroids.
- The evidence olopatadine (Patanase) is of uncertain validity. Available evidence includes four studies in patients with SAR and PAR.
- There is no evidence supporting the superiority of olopatadine (Patanase) over other intranasal antihistamines, or over oral antihistamines in the treatment of SAR.

Decision

- Ciclesonide (Omnaris) is non-preferred/non-formulary because there are generic and preferred/formulary brand options for this class of medication that address the needs of most patients.
- Olopatadine (Patanase) is non-preferred/non-formulary because there is no evidence it is superior to preferred/formulary options.

Products

Drug Products	FDA approval ^a	Patent Expiration(s) ^c	FDA approved indications	Usual Dose/Route	Potential Off-label Uses ^d
beclomethasone (Beconase AQ [®])	7/1987	expired	<ul style="list-style-type: none"> • Rhinitis, allergic or non-allergic; seasonal or perennial • Nasal polyps • 5yr and above 	1-2 sprays/nostril QD to BID	
budesonide (Rhinocort Aqua [®])	10/1999	4/2017	<ul style="list-style-type: none"> • Rhinitis, allergic and non-allergic • 6 yr and older 	1-4 sprays/nostril once daily	Nasal polyps
ciclesonide (Omnaris)	10/2006	1/2013	<ul style="list-style-type: none"> • Allergic rhinitis seasonal or perennial • 6yr and above 	2 sprays/nostril once daily	
flunisolide (Nasarel [®])	3/1995	expired	<ul style="list-style-type: none"> • Seasonal or Perennial allergic rhinitis • 6 yr and older 	1- 2 sprays/nostril BID to TID	Eosinophilic nonallergic rhinitis Sinusitis
fluticasone furoate	05/2007	08/2021	<ul style="list-style-type: none"> • Allergic rhinitis, 	1-2 sprays/nostril	

(Veramyst [®])			Seasonal and perennial • 2 yr and above	once daily	
fluticasone propionate (Flonase [®])	10/1994	expired	• Allergic rhinitis, Rhinitis, Non-allergic • 4 yr and older	1- 2 sprays/nostril once daily	Nasal polyp
mometasone (Nasonex [®])	10/1997	7/2014	• Allergic rhinitis, Seasonal allergic rhinitis • Nasal polyps • 2 yr and above	1-2 sprays/nostril once daily	Rhinitis; Adjunct - Sinusitis; Adjunct
triamcinolone (Nasacort AQ [®])	5/1996	7/2016	• Allergic rhinitis, perennial or seasonal • 6 yr and older	1-2 sprays/nostril once daily	
olopatadine (Patanase)	4/2008	12/2010	• Seasonal allergic rhinitis • 12 yr and older	2 sprays/nostril twice daily	
azelastine (Astelin)	11/1996	11/2010	• Seasonal allergic rhinitis • Vasomotor rhinitis • 5yr and above	1-2 sprays/nostril twice daily	
ipratropium bromide (intranasal)	10/1995	Expired	• rhinorrhea associated w/ allergic & nonallergic perennial rhinitis • 6 yr and older	2 sprays/nostril BID to TID	

^a Date applies to approval date for the original brand name medication where there are now generics available.

^c Based on patents listed in Orange Book as of 07/22/2008.

^d As listed in © 1974 - 2008 Thomson MICROMEDEX database or as referenced.

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