



Therapeutic Class ReviewSM

Nasal – Fluticasone Furoate (Veramyst[®])

February 2008

New Product for Review:

fluticasone furoate (Veramyst[®])[GlaxoSmithKline]

Dossier Provided by Manufacturer:

Dossier Evaluation: (1)

- 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

- Fluticasone furoate (Veramyst) is an intranasal corticosteroid indicated for the treatment of the symptoms of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in patients 2 years of age and older.
- Fluticasone furoate (Veramyst) was approved by the FDA on April 27, 2007 and is currently available.
- Fluticasone propionate (Flonase) is available generically.
- In the U.S., allergic rhinitis affects up to 40 million people annually.
- Fluticasone furoate (Veramyst) is more expensive than the generically available inhaled nasal steroids, and is also more expensive than some of the preferred/ formulary brand nasal steroids.

Evidence

- The evidence fluticasone furoate (Veramyst) is of uncertain validity. Available evidence includes:
 - Six studies in patients with SAR.
 - Three studies in patients with PAR.
- There is no evidence supporting superiority of fluticasone furoate (Veramyst) over other intranasal corticosteroids in the treatment of SAR or PAR.
- There is no direct evidence of differences in harms between fluticasone furoate (Veramyst) and other intranasal corticosteroids.

Decision

Fluticasone furoate (Veramyst) 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.

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 5yrs and above 	1-2 sprays EN QD to BID nasal	
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 EN QD nasal	Nasal polyps
ciclesonide (Omnaris)	10/2006	1/2013	<ul style="list-style-type: none"> Allergic rhinitis 12ys and above 	2 sprays (50 mcg/spray) EN QD nasal	
flunisolide (Nasarel [®])	3/1995	6/2007	<ul style="list-style-type: none"> Seasonal or Perennial allergic rhinitis 6 yr and older 	1- 2 sprays EN TID 2 sprays EN BID MAX 8 sprays/EN/day nasal	Eosinophilic nonallergic rhinitis Sinusitis
fluticasone furoate (Veramyst [®])	05/2007	08/2021	<ul style="list-style-type: none"> Allergic rhinitis, Seasonal and perennial 2 ys and above 	1-2 sprays EN QD nasal	
fluticasone propionate (Flonase [®])	10/1994		<ul style="list-style-type: none"> Allergic rhinitis, Rhinitis, Non-allergic 4 y and older 	1- 2 sprays EN QD MAX 2 sprays/nostril/day nasal	Nasal polyp
mometasone (Nasonex [®])	10/1997	7/2014	<ul style="list-style-type: none"> Allergic rhinitis, Seasonal allergic rhinitis Nasal polyps 2 ys and above 	1-2 sprays/nostril once daily nasal	Rhinitis; Adjunct - Sinusitis; Adjunct
triamcinolone (Nasacort AQ [®])	5/1996	7/2016	<ul style="list-style-type: none"> Allergic rhinitis, perennial or seasonal 6 yr and older 	1-2 metered sprays (55 mcg/spray) in each nostril once a day nasal	

^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 09/20/2007.

^d As listed in © 1974 - 2007 Thomson MICROMEDEX database or as referenced.

References

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