



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.

Available Therapeutic Alternatives:

Preferred/Formulary	Non-Preferred/Non-Formulary
budesonide (Rhinocort Aqua [®]) [AstraZeneca]	beclomethasone (Beconase AQ [®]) [GSK]
flunisolide (Nasarel [®]) [various]	fluticasone furoate (Veramyst [®])[GSK]
fluticasone (Flonase [®]) [various]	ciclesonide (Omnaris) [Altana]
mometasone (Nasonex [®]) [Schering]	
triamcinolone (Nasacort AQ [®]) [Aventis]	

* Covered with prior authorization

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.
- **Considerations in Subpopulations:**
 - **Pediatrics:** Corticosteroids may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth routinely of pediatric patients receiving fluticasone furoate (Veramyst). ^[1]
 - **Geriatrics:** Clinical studies of fluticasone furoate (Veramyst) did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently than younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. ^[1]
 - **Hepatic Impairment:** Use with caution in patients with severe hepatic impairment as it may increase exposure to fluticasone furoate.

Expert opinion

Expert opinion was sought from 26 providers including primary care physicians and allergists. Comments included were:

- Not familiar with the product
- Would not use Veramyst until it had been out and used and proven
- Had used it and patients liked it and they thought it was slightly better than Flonase and Nasonex
- Would not use Veramyst over generic steroids, unless cheaper

Product Value

Fluticasone furoate (Veramyst) is another treatment option for patients with allergic rhinitis. It is more expensive than generic options that are currently available, and for pediatrics patients between the ages of 2-4 years of age, there are preferred formulary alternatives that are more cost effective.

Conclusion

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	Cost ^b	Potential Off-label Uses ^d
beclomethasone (Beconase AQ [®])	7/1987	mo/yr	<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	\$113.78	
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	\$91.80	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	No pricing available	
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	\$28.75	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	\$94.74	
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	\$48.00	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	\$91.49	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	\$93.19	

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

^b Cost estimate based on AWP (average wholesale price) listed in First Data Bank as of June 2007 for 1 month of therapy.

^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.

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