



Therapeutic Class ReviewSM

Mometasone furoate inhalation powder (Asmanex)[®] Twisthaler[®] [Schering-Plough]

February 2006

New Product for Review:

Mometasone Furoate (Asmanex[®] Twisthaler[®])

Dossier Provided by Manufacturer:

Dossier Evaluation: 3

- 1- dossier w/missing components
- 2- all components present, except pharmacoeconomic model
- 3- all components present (comprehensive)

Executive Summary

- Mometasone furoate inhalation (Asmanex) is indicated:
 - For maintenance or prophylactic treatment of asthma in patients 12 years of age and older.
To reduce or eliminate the need for oral corticosteroids in asthma patients who require oral corticosteroid therapy.

Evidence

- The evidence for mometasone furoate inhalation (Asmanex) for in the treatment of severe persistent asthma is possibly useful.
 - Mometasone furoate inhalation (Asmanex) decreased the daily need for oral corticosteroids in patients with severe asthma who had been maintained on steroids.
 - Mometasone furoate inhalation (Asmanex) also improved various pulmonary function measures over baseline.
- The evidence for mometasone furoate inhalation (Asmanex) in other severity levels of asthma (mild-to-moderate and moderate persistent asthma) is uncertain.
- There is no useful evidence that mometasone furoate inhalation (Asmanex) is more effective than other inhaled corticosteroids when used in patients with asthma.
- There is no useful evidence that mometasone furoate inhalation (Asmanex) has a side-effect profile that differs significantly from other inhaled corticosteroids when used in patients with asthma.

Decision

- Add mometasone furoate inhalation (Asmanex) as preferred/formulary because :
 - Effectiveness is demonstrated in at least one randomized controlled trial (RCT).
 - There is at least similar efficacy to other inhaled corticosteroids without adding cost risk.
 - Addition will provide additional therapeutic choice for patients and physicians.

I. Products¹⁻⁷

Drug Products	FDA approval	FDA approved indications ¹⁻⁷	Medium Daily Dose [‡] ₁₈	Dose / puff	Potential Off-label Uses [†]
Triamcinolone Acetonide (Azmacort) [Kos]	04/1982	Maintenance and prophylactic treatment of asthma including patients who require systemic corticosteroids and may benefit from systemic dose reduction/elimination. ≥ 6 years of age	Adult 1000–2000 mcg Child 800-1200 mcg	100 mcg/puff	COPD
Fluticasone Propionate (Flovent HFA) [GlaxoSmithKline]	05/2004	Maintenance and prophylactic treatment of asthma including patients who require systemic corticosteroids and may benefit from systemic dose reduction/elimination. ≥ 12 years of age	Adult: 264–660 mcg	44 µg 110 µg, 220 mcg	COPD Chronic Bronchitis
Budesonide (Pulmicort Turbuhaler Pulmicort Respules) [AstraZeneca]	06/1997 08/2000	Turbuhaler: Maintenance and prophylactic treatment of asthma; includes patients who require systemic corticosteroids and may benefit from systemic dose reduction/elimination. ≥ 6 years of age Respules Maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.	Turbuhaler Adult 400–600 mcg Child 400–800 mcg Respules Child 1 mg	Turbuhaler 200 mcg Respules 250 mcg/amp 500 mcg/amp	COPD
Beclomethasone Dipropionate (QVAR) [IVAX]	09/2000	Maintenance and prophylactic treatment of asthma including patients who require systemic corticosteroids and may benefit from systemic dose reduction/elimination. ≥ 5 years of age	Adult: 504–840 mcg Child: 160–320 mcg	40 mcg 80 mcg	COPD
Flunisolide (AeroBid/AeroBid-M) [Forest]	08/1984	Maintenance and prophylactic treatment of asthma including patients who require systemic corticosteroids and may benefit from systemic dose reduction/elimination. ≥ 6 years of age	Adult 1000–2000 mcg Child 1000–1250 mcg	250 mcg	COPD
Mometasone Furoate (Mometasone furoate inhalation (Asmanex) Twisthaler) [Schering]	03/2005	Maintenance and prophylactic treatment of asthma including patients who require systemic corticosteroids and may benefit from systemic dose reduction/elimination. ≥ 12 years of age	Adult 220 mcg – 440 mcg [‡]	220 mcg /unit	unknown

[†] As listed in © 1974 - 2005 Thomson MICROMEDEX database or as referenced.

[‡] Dosing is based on National Heart Lung and Blood Institute (NHLBI) guidelines listing medium doses of ICS products. Mometasone furoate inhalation (Asmanex) is not yet listed in the NHLB guidelines; therefore dosing is based in package insert recommendations.

References

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