# Aerospan (flunisolide)

| STRENGTH | DOSAGE FORM | ROUTE | GPID |
|---|---|---|---|
| 80mcg/actuation 8.9 g/canister | HFA aerosol inhaler w/ adapter | Inhaled | 35718 |

**MANUFACTURER**

Meda Pharmaceuticals

**INDICATION**

Aerospan Inhalation Aerosol is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age and older. Aerospan Inhalation Aerosol is also indicated for asthma patients requiring oral corticosteroid therapy, where adding Aerospan Inhalation Aerosol may reduce or eliminate the need for oral corticosteroids.

Aerospan Inhalation Aerosol is NOT indicated for the relief of acute bronchospasm.

**DRUG CLASS**

GLUCOCORTICOIDS, ORALLY INHALED

**PLACE IN THERAPY**

Aerospan HFA is a corticosteroid inhaler that includes a two-piece plastic purple actuator and gray spacer assembly with the canister. Each 8.9 g canister provides 120 metered actuations.

Other corticosteroid inhalers available include: Asmanex (mometasone), Flovent (fluticasone), Pulmicort (budesonide), Qvar (beclomethasone) and Alvesco (ciclesonide).

Aerospan HFA does not contain chlorofluorocarbons (CFCs).

Airway inflammation in both large and small airways is an important component in the pathogenesis of asthma. Corticosteroids have been shown to have a wide range of anti-inflammatory effects, inhibiting both inflammatory cells and release of inflammatory mediators. It is presumed that these anti-inflammatory actions play an important role in the efficacy of flunisolide in controlling symptoms and improving lung function in asthma. Inhaled flunisolide most likely acts topically at the site of deposition in the bronchial tree after inhalation.

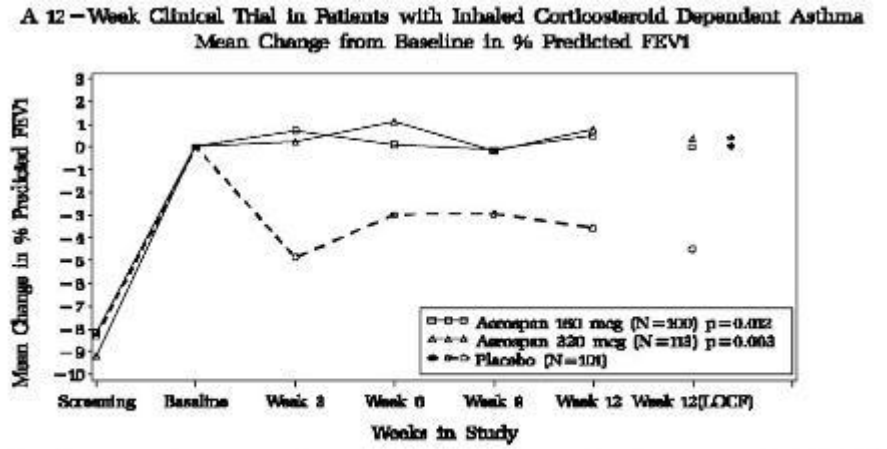
**EFFICACY**

The efficacy of Aerospan has been studied in two double-blind, parallel, placebo-and active-controlled clinical studies of 12 weeks duration involving more than 1250 patients. Studies had a 2-week run-in period followed by a 12-week randomized treatment period. During the run-in period all patients received flunisolide CFC inhalation aerosol 500 mcg twice daily. Patients were then randomized to double-blind treatment with different doses of Aerospan Inhalation Aerosol or flunisolide CFC inhalation aerosol and monitored for lung function changes to see if they maintained, improved, or lost stability.

Baseline was assessed at the end of the run-in period. The primary endpoint was the change from baseline in percent predicted FEV1 after 12 weeks treatment.

**Adult and Adolescent Patients with Asthma**

Efficacy was evaluated in 669 asthma patients (which included 581 adults and 88 children who were 12-17 years of age). The primary endpoint was change from baseline in percent predicted FEV1 at 12 weeks. In primary endpoint, patients in the placebo group deteriorated 4.3% from baseline after 12 weeks whereas patients treated with Aerospan Inhalation Aerosol 160 mcg or 320 mcg twice daily maintained FEV1 over the course of the study. Aerospan Inhalation Aerosol 160 and 320 mcg twice daily provided statistically significant results (see Figure below) over placebo. However, the 80 mcg dose provided no significant advantage when compared to placebo. Furthermore, Aerospan Inhalation Aerosol and flunisolide CFC inhalation aerosol gave comparable results.



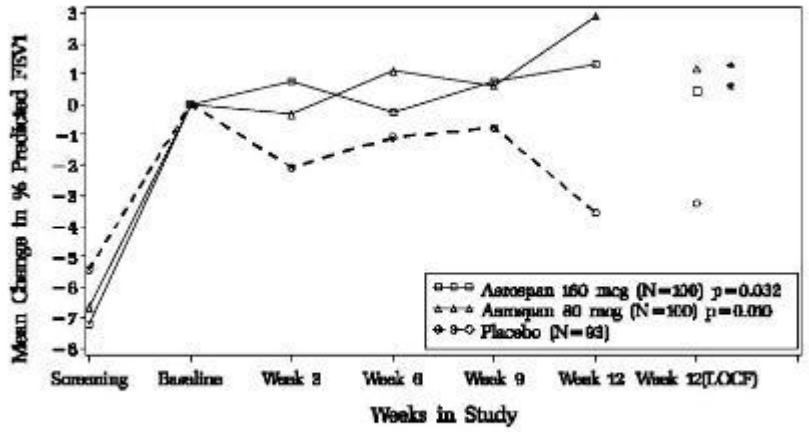

The primary endpoint was the change from baseline in % Predicted FEV1 at Week 12 (LOCF).
Each p-value is for the comparison of the Aerospan dose level versus placebo.
* Indicates a statistically significant difference from placebo.

Obtained from Aerospan Inhalation Aerosol package insert

**Pediatric Patients with Asthma**

Although the study enrolled 583 pediatric asthma patients who were 4 to 11 years of age, the primary efficacy parameter only evaluated 513 patients who were ages 6 to 11 years. Patients were randomized to Aerospan Inhalation Aerosol 80 mcg or 160 mcg twice daily, flunisolide CFC inhalation aerosol 250 mcg or 500 mcg twice daily, or placebo. The primary endpoint was change from baseline in percent predicted FEV1 at 12 weeks in patients 6 years of age and older. In primary endpoint, patients in the placebo group deteriorated 4.0% from baseline after 12 weeks, whereas patients treated with Aerospan Inhalation Aerosol 80 mcg or 160 mcg twice daily maintained FEV1 over the course of the study. When compared to placebo, Aerospan Inhalation Aerosol 80 mcg and 160 mcg dosages provided statistically significant results. However, the 160 mcg BID dosage was not significantly better than the 80 mcg BID dose (see Figure below). Aerospan Inhalation Aerosol and flunisolide CFC inhalation aerosol gave comparable results in patients 6 years of age and older.

A 12−Week Clinical Trial in Pediatric Patients (Age 6 − 11 years) with Mild to Moderate Asthma
Mean Change from Baseline in % Predicted FEV1




The primary endpoint was the change from baseline in % Predicted FEV1 at Week 12 (LOCF).
Each p−value is for the comparison of the Aerospan dose level versus placebo.
* Indicates a statistically significant difference from placebo.

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**SAFETY**

Aerospan is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

Safety and efficacy of Aerospan has not been studied in patients less than 4 years of age. In clinical trials, the adverse event profile observed in patients was similar between all age groups (4-5, 6-11, 12-17 years and older).

**Adverse Events with >3% incidence reported in controlled clinical studies with AEROSPAN Inhalation Aerosol (% of patients)**

| ADVERSE EVENT | PLACEBO (n = 220) | AEROSPAN Inhalation Aerosol | | |
|---|---|---|---|---|
| | | 80 MCG (n = 189) | 160 MCG (n = 217) | 320 MCG (n = 113) |
| BODY AS A WHOLE | | | | |
| Headache | 12.7 | 9.0 | 13.8 | 8.8 |
| Fever | 5.0 | 6.9 | 3.7 | 0.9 |
| Allergic Reaction | 2.3 | 4.2 | 4.6 | 4.4 |
| Pain | 3.6 | 2.6 | 4.6 | 1.8 |
| Accidental Injury | 2.3 | 3.7 | 3.7 | 3.5 |
| Infection, Bacterial | 0.9 | 3.7 | 0.9 | 0.9 |
| Back Pain | 2.3 | 0.5 | 3.2 | 1.8 |
| DIGESTIVE SYSTEM | | | | |
| Vomiting | 4.1 | 4.2 | 4.6 | 0.0 |
| Dyspepsia | 1.4 | 2.1 | 3.2 | 3.5 |
| RESPIRATORY SYSTEM | | | | |
| Pharyngitis | 13.2 | 17.5 | 16.6 | 16.8 |
| Rhinitis | 10.0 | 9.0 | 15.7 | 3.5 |
| Cough Increased | 7.7 | 8.5 | 5.5 | 1.8 |
| Sinusitis | 5.5 | 7.4 | 4.1 | 8.8 |
| Epistaxis | 0.9 | 3.2 | 0.9 | 0.0 |
| SKIN AND APPENDAGES | | | | |
| Rash | 3.2 | 2.6 | 3.7 | 1.8 |
| UROGENITAL SYSTEM | | | | |
| Urinary Tract Infection | 0.5 | 1.1 | 0.9 | |

**DOSAGE**

**Adults:**
The recommended adult dose is 2 actuations (160 mcg) inhaled PO twice daily; may titrate upward, not to exceed 4 actuations (320 mcg) twice daily.

**Pediatrics:**

- For children <6 years, Aerospan Inhalation Aerosol is NOT indicated.
- For children 6-11 years: 1 actuation (80 mcg) inhaled PO twice daily initially; may titrate upward, not to exceed 2 actuations (160 mcg) twice daily.
- For children ≥12 years: 2 actuations (160 mcg) inhaled PO twice daily; may titrate upward, not to exceed 4 actuations (320 mcg) twice daily.

**COST**

| Drug | Cost/unit | Cost per 30 days* |
|---|---|---|
| Aerospan (flunisolide) Inhalation Aerosol 80mcg | $194 | $388 |
| Asmanex (mometasone) Twisthaler 110mcg, 220mcg | $158-287 | $287 |
| Flovent (fluticasone) Diskus 50mcg, 100mcg, 250mcg | $144-$203 | $407 |
| Flovent (fluticasone) HFA 44mcg, 110mcg, 220mcg | $152-$317 | $317 |
| Pulmicort (budesonide) Flexhaler 90mcg, 180mcg | $144-$193 | $385 |
| Qvar (beclomethasone) inhaler 40mcg, 80mcg | $87-$191 | $384 |
| Alvesco (ciclesonide) inhaler 80mcg, 160mcg | $207 | $417 |

*Based on maximum dosage

**FORMULARY PLACEMENT RECOMMENDATIONS**

Based on this initial assessment of available clinical and financial information, consider NOT ADDING Aerospan Inhalation Aerosol to the formulary pending complete review by the appropriate oversight committee for the plan.

**REFERENCES**


- Aerospan [Prescribing Information]. Accessed on December 20, 2013. Available at http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=0e996cf8-6975-452a-a84c-ca1033a629b1