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Ciclesonide Inhalation Aerosol (Alvesco)

??? ??????: 30 ??????/?????? 2017

Systemic and local corticosteroid use may result in the following:

- **WARNINGS AND PRECAUTIONS** infection [see *Candida albicans*]
- **WARNINGS AND PRECAUTIONS** Immunosupression [see]
- **WARNINGS AND PRECAUTIONS** Hypercorticism and adrenal suppression [see]
- **WARNINGS AND PRECAUTIONS** Growth effects [see]
- **WARNINGS AND PRECAUTIONS** Glaucoma and cataracts [see]

Clinical Trial Experience

The safety data described below for adults and adolescents 12 years of age and older reflect exposure to ALVESCO in doses ranging from 80 mcg to 640 mcg twice daily in five double-blind placebo-controlled clinical trials. Studies with once daily dosing are omitted from the safety database because the doses studied once daily are lower than the highest recommended twice daily doses. The five studies were of 12 to 16 weeks treatment duration, one of which included a safety extension follow up of one year. In the 12 to 16 week treatment studies, 720 patients (298 males and 422 females) aged 12 years and older were exposed to ALVESCO. In the long-term safety trial, 197 patients (82 males and 115 females) with severe persistent asthma from one of the 12-week trials were re-randomized and treated for up to one year with ALVESCO 320 mcg twice daily. Safety information for pediatric patients 4 to 11 years of age, is obtained from once daily dosing studies. Two of these studies were designed with a 12-week double-blind treatment period followed by a long-term open label safety extension of one year, and one study was an open label safety study of one year duration [see **Pediatric Use**].

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adult and Adolescent 12 Years of Age and Older

Four of the five trials included a total of 624 patients ages 12 years and older (359 females and 265 males) with asthma of varying severity who were treated with ALVESCO 80 mcg, 160 mcg, or 320 mcg twice daily for 12 to 16 weeks. These studies included patients previously using either controller therapy (predominantly inhaled corticosteroids) or reliever therapy (bronchodilator therapy alone). In these trials, the mean age was 39.1 years, and the majority of the patients (79.0%) were Caucasian. In these trials, 52.3%, 59.8% and 54.1% of the patients in the ALVESCO 80 mcg, 160 mcg, and 320 mcg treatment groups, respectively, had at least one adverse event compared to 58.0% in the placebo group.

Table 1 includes adverse reactions for the recommended doses of ALVESCO that occurred at an incidence of ? 3% in any of the ALVESCO groups and which were more frequent with ALVESCO compared to placebo.

Table 1: Adverse Reactions with ? 3% Incidence Reported in Patients ? 12 Years of Age with ALVESCO in US Placebo-Controlled Clinical Trials in Patients Previously on Bronchodilators and/or Inhaled Corticosteroids

	ALVESCO			Placebo	
Adverse Reaction	80 mcg BID (N=325) %	160 mcg BID (N=127) %	320 mcg BID (N=172) %	(N=507) %	
Headache	4.9	11.0	8.7	7.3	
Nasopharyngitis	10.5	8.7	7.0	7.5	
Sinusitis	3.1	5.5	5.2	3.0	
Pharyngolaryngeal pain	4.3	2.4	4.7	4.3	
Upper respiratory Inf.	7.1	8.7	4.1	6.5	
Arthralgia	0.9	2.4	3.5	1.0	
Nasal congestion	1.8	5.5	2.9	1.6	
Pain in extremity	0.3	3.1	2.3	1.0	
Back pain	0.6	3.1	1.2	2.0	

The following adverse reactions occurred in these clinical trials using ALVESCO with an incidence of less than 1% and occurred at a greater incidence with ALVESCO than with placebo.

candidiasis Oral **Infections and Infestations:**

Cough **Respiratory Disorders:**

Dry mouth, nausea**Gastrointestinal Disorders:**

Chest discomfort **General disorders and administrative site conditions:**

Dysphonia, dry throat **Respiratory, Thoracic, and Mediastinal Disorders:**

The fifth study was a 12-week clinical trial in asthma patients 12 years of age and older who previously required oral corticosteroids (average daily dose of oral prednisone of 12 mg/day), in which the effects of ALVESCO 320 mcg twice daily (n = 47) and 640 mcg twice daily (n = 49) were compared with placebo (n = 45) for the frequency of reported adverse reactions. The following adverse reactions occurred at an incidence of ? 3% in the ALVESCO-treated patients and were more , influenza, pneumonia, nasopharyngitis, arthralgia, back pain, musculoskeletal chest pain, *candidiasis*frequent compared to placebo: sinusitis, hoarseness, oral headache, urticaria, dizziness, gastroenteritis, face edema, fatigue, and conjunctivitis.

Pediatric Patients less than 12 Years of Age

The safety of ALVESCO in pediatric patients 4 to 11 years of age was evaluated in two studies in which ALVESCO 40 mcg, 80 mcg, and 160 mcg was administered once daily for 12 weeks and in one study in pediatric patients 2 to 6 years of age in which ALVESCO 40 mcg, 80 mcg, and 160 mcg was administered once daily for]**Pediatric Use**24 weeks. Studies have not been conducted in patients less than 2 years of age. [see

Long-Term Clinical Trials Experience

A total of 197 patients 12 years of age and older (82 males and 115 females) from one of the 12-week treatment placebo-controlled studies were re-randomized to ciclesonide 320 mcg twice daily and followed for one year. The safety profile from the one-year follow up was similar to that seen in the 12- and 16-week treatment].**Pediatric Use**studies. Long term safety information for pediatric patients 4 to 11 years of age is obtained from three open label one year safety studies [see

Post-marketing Experience

In addition to adverse reactions identified from clinical trials, the following adverse reactions have been identified during worldwide post-marketing use of ciclesonide oral inhalation. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Immediate or delayed hypersensitivity reactions such as angioedema with swelling of the lips, tongue and pharynx.