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Breo Ellipta (Fluticasone Furoate and Vilanterol Inhalation Powder)

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

LABA, such as vilanterol, one of the active ingredients in BREO ELLIPTA, increase the risk of asthma-related death. BREO ELLIPTA is not indicated for the]**WARNINGS AND PRECAUTIONS** and **BOXED WARNINGS**treatment of asthma. [See

Systemic and local corticosteroid use may result in the following:

-]**WARNINGS AND PRECAUTIONS** Increased risk of pneumonia in COPD [see
-]**WARNINGS AND PRECAUTIONS** Increased risk for decrease in bone mineral density [see

Clinical Trials Experience

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

The clinical program for BREO ELLIPTA included 7,700 subjects with COPD in two 6-month lung function trials, two 12-month exacerbation trials, and 6 other trials of shorter duration. A total of 2,034 subjects have received at least 1 dose of BREO ELLIPTA 100 mcg/25 mcg, and 1,087 subjects have received higher doses of fluticasone furoate/vilanterol. The safety data described below are based on the confirmatory 6-month and 12-month trials. Adverse reactions observed in the other trials were similar to those observed in the confirmatory trials.

6-Month Trials

The incidence of adverse reactions associated with BREO ELLIPTA in Table 1 is based on 2 placebo-controlled, 6-month clinical trials (Trials 1 and 2; n = 1,224 and n = 1,030, respectively). Of the 2,254 subjects, 70% were male and 84% were Caucasian. They had a mean age of 62 years and an average smoking history of 44 was 48% (range: 14% to 87%), the mean $_1$pack years, with 54% identified as current smokers. At screening, the mean postbronchodilator percent predicted FEV /forced vital capacity (FVC) ratio was 47% (range: 17% to 88%), and the mean percent reversibility was 14% (range: -41% to 152%).$_1$ postbronchodilator FEV

Subjects received 1 inhalation once daily of the following: BREO ELLIPTA 100 mcg/25 mcg, fluticasone furoate/vilanterol 50 mcg/25 mcg, fluticasone furoate/vilanterol 200 mcg/25 mcg, fluticasone furoate 100 mcg, fluticasone furoate 200 mcg, vilanterol 25 mcg, or placebo.

Table 1: Adverse Reactions With ? 3% Incidence and More Common Than Placebo With BREO ELLIPTA in Subjects With Chronic Obstructive Pulmonary Disease

Placebo (n = 412) %	Fluticasone Furoate 100 mcg (n = 410) %	Vilanterol 25 mcg (n = 408) %	BREO ELLIPTA 100 mcg/25 mcg (n = 410) %	Adverse Event
				Infections and infestations
8	8	10	9	Nasopharyngitis
3	4	5	7	Upper respiratory tract infection
2	3	2	5	Oropharyngeal [a]candidiasis
				Nervous system disorders
5	7	9	7	Headache

[a] Includes terms oral candidiasis, oropharyngeal candidiasis, candidiasis, and oropharyngitis fungal.

12-Month Trials

Long-term safety data is based on two 12-month trials (Trials 3 and 4; n = 1,633 and n = 1,622, respectively). Trials 3 and 4 included 3,255 subjects, of which 57% were male and 85% were Caucasian. They had a mean age of 64 years and an average smoking history of 46 pack years, with 44% identified as current smokers. /FVC ratio was 46% $_1$was 45% (range: 12% to 91%), and the mean postbronchodilator FEV $_1$At screening, the mean postbronchodilator percent predicted FEV (range: 17% to 81%), indicating that the subject population had moderate to very severely impaired airflow obstruction. Subjects received 1 inhalation once daily of the following: BREO ELLIPTA 100 mcg/25 mcg, fluticasone furoate/vilanterol 50 mcg/25 mcg, fluticasone furoate/vilanterol 200 mcg/25 mcg, or vilanterol 25 mcg. In addition to the events shown in Table 1, adverse reactions occurring in greater than or equal to 3% of the subjects treated with BREO ELLIPTA (N = 806) for 12], bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, **WARNINGS AND PRECAUTIONS**months included COPD, back pain, pneumonia [see influenza, pharyngitis, diarrhea, peripheral edema, and pyrexia.