Skip to main content

Aclidinium Bromide (Tudorza Pressair)

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

The following adverse reactions are described in greater detail in other sections:

- **WARNINGS AND PRECAUTIONS** Paradoxical bronchospasm [see]
- **WARNINGS AND PRECAUTIONS** Worsening of narrow-angle glaucoma [see]
- **WARNINGS AND PRECAUTIONS** Worsening of urinary retention [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 to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

3-Month and 6-Month Trials

TUDORZA PRESSAIR was studied in two 3-month (Trials B and C) and one 6-month (Trial D) placebo-controlled trials in patients with COPD. In these trials, 636 patients were treated with TUDORZA PRESSAIR at the recommended dose of 400 mcg twice daily.

The population had a mean age of 64 years (ranging from 40 to 89 years), with 58% males, 94% Caucasian, and had COPD with a mean pre-bronchodilator forced expiratory volume in one second (FEV_1) percent predicted of 48%. Patients with unstable cardiac disease, narrow-angle glaucoma, or symptomatic prostatic hypertrophy or bladder outlet obstruction were excluded from these trials.

Table 1 shows all adverse reactions that occurred with a frequency of greater than or equal to 1% in the TUDORZA PRESSAIR group in the two 3-month and one 6-month placebo-controlled trials where the rates in the TUDORZA PRESSAIR group exceeded placebo.

Table 1: Adverse Reactions (% Patients) in Placebo-Controlled Clinical Trials

Treatment		Adverse Reactions
Placebo (N = 640) n (%)	TUDORZA PRESSAIR (N = 636) n (%)	Preferred Term
32 (5.0)	42 (6.6)	Headache
25 (3.9)	35 (5.5)	Nasopharyngitis
14 (2.2)	19 (3.0)	Cough
9 (1.4)	17 (2.7)	Diarrhea
5 (0.8)	11 (1.7)	Sinusitis
8 (1.2)	10 (1.6)	Rhinitis
5 (0.8)	7 (1.1)	Toothache
3 (0.5)	7 (1.1)	Fall
3 (0.5)	7 (1.1)	Vomiting

In addition, among the adverse reactions observed in the clinical trials with an incidence of less than 1% were diabetes mellitus, dry mouth, 1st degree AV block, osteoarthritis, cardiac failure, and cardio-respiratory arrest.

Long-term Safety Trials

TUDORZA PRESSAIR was studied in three long term safety trials, two double blind and one open label, ranging from 40 to 52 weeks in patients with moderate to severe COPD. Two of these trials were extensions of the 3-month trials, and one was a dedicated long term safety trial. In these trials, 891 patients were treated with TUDORZA PRESSAIR at the recommended dose of 400 mcg twice daily. The demographic and baseline characteristics of the long term safety trials were similar to those of the placebo-controlled trials. The adverse events reported in the long term safety trials were similar to those occurring in the placebo-controlled trials of 3 to 6 months. No new safety findings were reported compared to the placebo controlled trials.