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Alfuzosin HCl (Uroxatral)

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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 clinical practice.

The incidence of adverse reactions has been ascertained from 3 placebo-controlled clinical trials involving 1,608 men where daily doses of 10 and 15 mg alfuzosin were evaluated. In these 3 trials, 473 men received UROXATRAL (alfuzosin HCl) 10 mg extended-release tablets. In these trials, 4% of patients taking UROXATRAL (alfuzosin HCl) 10 mg extended-release tablets withdrew from the trial due to adverse reactions, compared with 3% in the placebo group.

Table 1 summarizes adverse reactions that occurred in ?2% of patients receiving UROXATRAL, and at a higher incidence than that of the placebo group. In general, the adverse reactions seen in long-term use were similar in type and frequency to the events described below for the 3-month trials.

Table 1 : Adverse Reactions Occurring in ?2% of UROXATRAL-Treated Patients and More Frequently than with Placebo in 3-Month Placebo-Controlled Clinical Trials

UROXATRAL (n=473)	Placebo (n=678)	Adverse Reaction
27 (5.7%)	19 (2.8%)	Dizziness
14 (3.0%)	4 (0.6%)	Upper respiratory tract infection
14 (3.0%)	12 (1.8%)	Headache
13 (2.7%)	12 (1.8%)	Fatigue

The following adverse reactions, reported by between 1% and 2% of patients receiving UROXATRAL and occurring more frequently than with placebo, are listed alphabetically by body system and by decreasing frequency within body system:

pain **Body as a whole:**

abdominal pain, dyspepsia, constipation, nausea **Gastrointestinal system:**

impotence **Reproductive system:**

bronchitis, sinusitis, pharyngitis **Respiratory system:**

The adverse reactions related to orthostasis that occurred in the double-blind phase 3 trials with alfuzosin **Signs and Symptoms of Orthostasis in Clinical Trials:** 10 mg are summarized in Table 2. Approximately 20% to 30% of patients in these trials were taking antihypertensive medication.

Table 2: Number (%) of Patients with Symptoms Possibly Associated with Orthostasis in 3-Month Placebo-Controlled Clinical Trials

UROXATRAL (n=473)	Placebo (n=678)	Symptoms
27 (5.7%)	19 (2.8%)	Dizziness
2 (0.4%)	0	Hypotension or postural hypotension
1 (0.2%)	0	Syncope

Testing for blood pressure changes or orthostatic hypotension was conducted in three controlled studies. Decreased systolic blood pressure (?90 mm Hg, with a decrease ?20 mm Hg from baseline) was observed in none of the 674 placebo patients and 1 (0.2%) of the 469 UROXATRAL patients. Decreased diastolic blood pressure (?50 mm Hg, with a decrease ?15 mm Hg from baseline) was observed in 3 (0.4%) of the placebo patients and in 4 (0.9%) of the UROXATRAL patients. A positive orthostatic test (decrease in systolic blood pressure of ?20 mm Hg upon standing from the supine position) was seen in 52 (7.7%) of placebo patients and in

31 (6.6%) of the UROXATRAL patients.

Post-Marketing Experience

The following adverse reactions have been identified during post approval use of UROXATRAL. 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.

edema **General disorders:**

tachycardia, chest pain, angina pectoris in patients with pre-existing coronary artery disease, atrial fibrillation **Cardiac disorders:**

diarrhea **Gastrointestinal disorders:**

hepatocellular and cholestatic liver injury (including cases with jaundice leading to drug discontinuation) **Hepatobiliary disorders:**

rhinitis **Respiratory system disorders:**

priapism **Reproductive system disorders:**

rash, pruritis, urticaria, angioedema, toxic epidermal necrolysis **Skin and subcutaneous tissue disorders:**

flushing **Vascular disorders:**

thrombocytopenia **Blood and lymphatic system disorders:**

During cataract surgery, a variant of small pupil syndrome known as Intraoperative Floppy Iris Syndrome (IFIS) has been reported in some patients on or previously].**WARNINGS AND PRECAUTIONS**treated with alpha adrenergic antagonists [see