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Edarbi (azilsartan medoxomil)

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

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.

A total of 4814 patients were evaluated for safety when treated with Edarbi at doses of 20, 40, or 80 mg in clinical trials. This includes 1704 patients treated for at least six months; of these, 588 were treated for at least one year.

-Treatment with Edarbi was well-tolerated with an overall incidence of adverse reactions similar to placebo. The rate of withdrawals due to adverse events in placebo controlled monotherapy and combination therapy trials was 2.4% (19/801) for placebo, 2.2% (24/1072) for Edarbi 40 mg, and 2.7% (29/1074) for Edarbi 80 mg. The most common adverse event leading to discontinuation, hypotension/orthostatic hypotension, was reported by 0.4% (8/2146) patients randomized to Edarbi 40 mg or 80 mg compared to 0% (0/801) patients randomized to placebo. Generally, adverse reactions were mild, not dose related, and similar regardless of age, gender, and race.

In placebo-controlled monotherapy trials, diarrhea was reported up to 2% in patients treated with Edarbi 80 mg daily compared with 0.5% of patients on placebo.

Other adverse reactions with a plausible relationship to treatment that have been reported with an incidence of ? 0.3% and greater than placebo in more than 3300 patients treated with Edarbi in controlled trials are listed below:

nausea **Gastrointestinal Disorders:**

asthenia, fatigue **General Disorders and Administration Site Conditions:**

muscle spasm **Musculoskeletal and Connective Tissue Disorders:**

dizziness, dizziness postural **Nervous System Disorders:**

cough **Respiratory, Thoracic, and Mediastinal Disorders:**

Clinical Laboratory Findings

In controlled clinical trials, clinically relevant changes in standard laboratory parameters were uncommon with administration of Edarbi.

Serum creatinine

Small reversible increases in serum creatinine are seen in patients receiving 80 mg of Edarbi. The increase may be larger when coadministered with chlorthalidone or hydrochlorothiazide.

In addition, patients taking Edarbi who had moderate to severe renal impairment at baseline or who were > 75 years of age were more likely to report serum creatinine increases.

Hemoglobin/Hematocrit

Low hemoglobin, hematocrit, and RBC counts were observed in 0.2%, 0.4%, and 0.3% of Edarbi-treated subjects, respectively. None of these abnormalities were reported in the placebo group. Low and high markedly abnormal platelet and WBC counts were observed in < 0.1% of subjects.

Postmarketing Experience

The following adverse reactions have been identified during the postmarketing use of EDARBI. 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.

- Nausea
- Muscle spasms

- Rash
- Pruritus
- Angioedema