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Aceon (Perindopril Erbumine)

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Because clinical trials are conducted under widely varying conditions, adverse event 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.

Clinical Trials Experience

The following adverse reactions are discussed elsewhere in labeling:

- **WARNINGS AND PRECAUTIONS** Anaphylactoid reactions, including angioedema [see]
- **WARNINGS AND PRECAUTIONS** Hypotension [see]
- **WARNINGS AND PRECAUTIONS** Neutropenia and agranulocytosis [see]
- **WARNINGS AND PRECAUTIONS** Impaired renal function [see]
- **WARNINGS AND PRECAUTIONS** Hyperkalemia [see]
- **WARNINGS AND PRECAUTIONS** Cough [see]

Hypertension

ACEON has been evaluated for safety in approximately 3,400 patients with hypertension in U.S. and foreign clinical trials. The data presented here are based on results from the 1,417 ACEON-treated patients who participated in the U.S. clinical trials. Over 220 of these patients were treated with ACEON® (perindopril erbumine) for at least one year.

In placebo-controlled U.S. clinical trials, the incidence of premature discontinuation of therapy due to adverse events was 6.5% in patients treated with ACEON and 6.7% in patients treated with placebo. The most common causes were cough, headache, asthenia and dizziness.

Among 1,012 patients in placebo-controlled U.S. trials, the overall frequency of reported adverse events was similar in patients treated with ACEON and in those treated with placebo (approximately 75% in each group). The only adverse events whose incidence on ACEON was at least 2% greater than on placebo were cough (12% vs. 4.5%) and back pain (5.8% vs. 3.1%).

Dizziness was not reported more frequently in the perindopril group (8.2%) than in the placebo group (8.5%), but its likelihood increased with dose, suggesting a causal relationship with perindopril.

Stable Coronary Artery Disease

Perindopril has been evaluated for safety in EUROPA, a double-blind, placebo-controlled study in 12,218 patients with stable coronary artery disease. The overall rate of discontinuation was about 22% on drug and placebo. The most common medical reasons for discontinuation that were more frequent on perindopril than placebo were cough, drug intolerance and hypotension.

Postmarketing Experience

Voluntary reports of adverse events in patients taking ACEON that have been received since market introduction and are of unknown causal relationship to ACEON include: cardiac arrest, eosinophilic pneumonitis, neutropenia/agranulocytosis, pancytopenia, anemia (including hemolytic and aplastic), thrombocytopenia, acute renal failure, nephritis, hepatic failure, jaundice (hepatocellular or cholestatic), symptomatic hyponatremia, bullous pemphigoid, pemphigus, acute pancreatitis, falls, psoriasis, exfoliative dermatitis and a syndrome which may include: arthralgia/arthritis, vasculitis, serositis, myalgia, fever, rash or other dermatologic manifestations, a positive antinuclear antibody (ANA), leukocytosis, eosinophilia or an elevated erythrocyte sedimentation rate (ESR).

Clinical Laboratory Test Findings

Hematology

Small decreases in hemoglobin and hematocrit occur frequently in hypertensive patients treated with ACEON, but are rarely of clinical importance. In controlled clinical trials, no patient was discontinued from therapy due to the development of anemia. Leukopenia (including neutropenia) was observed in 0.1% of patients in **WARNINGS AND PRECAUTIONS**U.S. clinical trials [see].

Liver Function Tests

Elevations in ALT (1.6% ACEON versus 0.9% placebo) and AST (0.5% ACEON versus 0.4% placebo) have been observed in placebo-controlled clinical trials. The elevations were generally mild and transient and resolved after discontinuation of therapy.