

Benicar (olmesartan): Ongoing Safety Review

ISSUE: FDA is evaluating data from two clinical trials in which patients with type 2 diabetes taking the blood pressure medication, Benicar (olmesartan), an angiotensin II receptor blocker, had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. FDA's review is ongoing and the Agency has not concluded that Benicar increases the risk of death. FDA currently believes that the benefits of Benicar in patients with high blood pressure continue to outweigh its potential risks.

BACKGROUND: The Agency plans to review the primary data from the two studies of concern, ROADMAP and ORIENT, and is considering additional ways to assess the cardiovascular effects of Benicar. ROADMAP and ORIENT are both long-term clinical trials. In both trials, patients with type 2 diabetes were given either Benicar or placebo to determine if treatment with Benicar would slow the progression of kidney disease. An unexpected finding observed in both trials was a greater number of deaths from a cardiovascular cause (heart attack, sudden death, or stroke) in the Benicar-treated patients compared to placebo.

RECOMMENDATION: Follow the recommendations in the drug label when prescribing Benicar. Additional Information for Patients, for Healthcare Professionals and a Data Summary are provided in the Drug Safety Communication below. Additional information about ROADMAP and ORIENT can be found at clinicaltrials.gov.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Online: www.fda.gov/MedWatch/report.htm
- Phone: 1-800-332-1088