

WARNINGS

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SPECIAL WARNINGS ON CARDIOVASCULAR MORTALITY

(This subsection of labeling to be boxed, set in boldface type, and placed at the beginning of WARNINGS section of labeling.)

The administration of oral hypoglycemic drugs may be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin.

This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long term prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with maturity-onset nonketotic diabetes. The study involved 1,027 patients who were randomly assigned to one of five treatment groups (Diabetes, 19 (supp. 2): 747-830, 1970; Diabetes, 24 (supp. 1):65-184, 1975).