

13520 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

WARNINGS

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SPECIAL WARNING ON CARDIOVASCULAR MORTALITY

(Identical to boxed, boldface sulfonylurea labeling.)

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(Drug) is not adequate therapy in patients with juvenile diabetes or insulin-dependent diabetes at any age. Such patients should be treated with diet and insulin. The concomitant long term use of insulin and (drug) in an individual patient is, in view of the risk of increased cardiovascular mortality with (drug), less safe on a benefit-risk basis than the use of insulin alone.

The effectiveness of any oral hypoglycemic drug, including (drug), in lowering blood glucose to a desired level decreases in a large number of patients as the drug is administered over a period of months or years, in part because the patient's