

PROPOSED LABELING INDICATIONS, CONTRAINDICATIONS AND WARNINGS SECTIONS FOR ORAL HYPOGLYCEMIC DRUGS OF THE SULFONYLUREA CATEGORY.

INDICATIONS

(Drug) is indicated to control symptoms due to hyperglycemia in patients with maturity-onset nonketotic diabetes mellitus whose symptoms cannot be controlled by diet alone and in whom insulin cannot be used because of patient unwillingness, erratic adherence to the injection regimen, poor vision, physical or mental handicap, insulin allergy, employment requirements, or other similar factors.

(Drug) may also be used to lower blood glucose in asymptomatic patients whose blood glucose elevation cannot be controlled by diet alone and in whom insulin cannot be used for any of the above reasons. In considering the use of (drug) in asymptomatic patients, it should be recognized that whether or not controlling the blood glucose is effective in preventing the long term cardiovascular or neural complications of diabetes is an unanswered scientific question.

The use of (drug) may be associated with an increased risk of cardiovascular mortality as compared to diet alone or diet plus insulin; see WARNINGS. For this reason, it should be used only