FDA CURRENT DRUG INFORMATION

DIABETES PRESCRIBING INFORMATION

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ORAL HYPOGLYCEMIC AGENTS

SULFONYLUREAS

Following review of the findings of the University Group Diabetes Program (UGDP) on tolbutamide by FDA and several professional groups, FDA published last year* recommendations on the use of oral agents in the treatment of diabetes mellitus. The INDICATIONS AND WARNINGS section of the labeling of all sulfonylureas is now changed to read as follows:

INDICATIONS:

"Diet and reduction of excess weight are the foundation of therapy of diabetes mellitus and when the disease is adequately controlled by these measures, no other therapy is indicated.

". . . . . (Name of Drug) . . . . . is indicated in the treatment of adult-onset, non-ketotic diabetes mellitus which cannot be adequately controlled by diet and reduction of excess weight alone and when, in the judgment of the physician, insulin treatment is not feasible."

WARNINGS:

". . . . . (Name of Drug) . . . . . has been shown to lower excess sugar in the blood when administered in appropriate dosage to selected diabetic patients; this finding constitutes the basis of its use in such patients. Because the adult-onset, non-ketotic diabetes population is the only group in which adequate studies have shown the utility of the drug in the management of the condition, the use of *(Name of Drug)* should be limited to these patients as described in the indications section above.

"Twelve university medical clinics comprising the University Group Diabetes Program conducted a long-term prospective study designed to evaluate the efficacy of hypoglycemic drugs in the prevention of vascular complications in adult patients with recently diagnosed non-insulin dependent diabetes.

"All patients received diet instructions and, in addition, were randomly assigned to different treatment schedules (fixed dosages of tolbutamide, fixed dosage of insulin, variable dosage of insulin, or placebo). At the end of an eight-year period, the death rates from cardiovascular disease were 12.7% or 26 out of 204 patients in the tolbutamide group, and 4.9% or 10 out of 205 patients in the placebo group, whereas the cardiovascular death rates in the two insulin groups were similar to the rate in the placebo group. The reasons for the higher cardiovascular mortality in the tolbutamide group are not clear. These studies provided no evidence that the combination of diet and tolbutamide in the fixed dosage, as used for these mild non-insulin dependent diabetics, was more effective than diet alone in prolonging life. The findings suggested that tolbutamide and diet may be less effective, at least insofar as cardiovascular mortality is concerned, than diet alone or than diet and insulin.

"Although the UGDP study considered only one sulfonylurea, tolbutamide, drugs of this class are sufficiently alike in effects that the physician should be aware of the above results when prescribing any of them."

Full information of all labeling changes is now being sent to physicians directly from the manufacturers. Physicians are urged to familiarize themselves as soon as possible with the new labeling.

*FDA Current Drug Information, October 1970.