

Upjohn



# Orinase<sup>®</sup>

tolbutamide, Upjohn

The older maturity-onset adult diabetic patient with relatively mild, nonketotic diabetes.

#### **Orinase<sup>®</sup> (tolbutamide, Upjohn) 0.5 Gm tablets**

An orally active hypoglycemic agent principally indicated in relatively mild, adult, maturity-onset, nonketotic diabetes; also, as a supplement to insulin therapy in selected diabetic patients, it may effect a stabilization of labile diabetes and reduce insulin requirement. Certain patients intolerant to chlorpropamide therapy at usual therapeutic doses have subsequently been successfully managed with Orinase (tolbutamide).

Use in mild asymptomatic diabetic patients with abnormal glucose tolerance tests not responding to diet therapy may result in improvement of the glucose tolerance test.

Use in conjunction with phenformin is indicated when optimal control is not obtained with Orinase or phenformin alone.

**Contraindications:** Orinase alone is not effective in juvenile or growth-onset diabetes nor in unstable brittle diabetes where insulin therapy is required.

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Orinase should not be used: when diabetes is complicated by acidosis, ketosis, or coma, or when a history of repeated bouts of acidosis or coma is obtained; in the presence of other acute complications such as fever, severe trauma, or infections, and in patients with severe renal insufficiency. Insulin is indicated in these circumstances.

**Pregnancy warning:** The safety and usefulness of Orinase during pregnancy has not been established either from the standpoint of the mother or the fetus. Animal studies have demonstrated fetidical and teratogenic effects of doses of 1,000-2,500 mg/kg/day, but application to human subjects is unknown. Therefore, Orinase is not recommended for the pregnant diabetic, and when administering Orinase to women of childbearing age, these facts should be borne in mind.

**Precautions:** Diagnostic and therapeutic measures necessary for optimal control with insulin are also necessary with Orinase. The