

13510 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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 blood glucose tends to rise over time and in part because of diminished responsiveness to the drug. This phenomenon is known as secondary failure to distinguish it from primary failure in which the drug is ineffective in an individual patient at the time of its initial administration. See DOSAGE AND ADMINISTRATION.

Renal or hepatic insufficiency may cause elevated blood levels of (drug) and increase the risk of serious hypoglycemic reactions.

Pregnancy: (Data and interpretation related to reproduction and teratology studies to be supplied by manufacturer).

Prolonged severe hypoglycemia (4 to 10 days) has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. Neonatal hypoglycemia has been reported more frequently following use of the longer-acting agents. If (drug)