

13524 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

e. The physician should use special caution after initiating phenformin therapy, after increasing the drug dosage, and in circumstances that may cause dehydration leading to impaired renal function.

f. Alcohol is known to potentiate the effect of phenformin in elevating blood lactate levels, and patients should be warned against excessive alcoholic intake while receiving phenformin.

g. Impaired hepatic function has been associated with some cases of lactic acidosis. Particular caution must be observed when administering (drug) to patients with hepatic disease.

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

PRECAUTIONS

Hypoglycemia: Hypoglycemia is unusual in patients receiving (drug) alone, but may occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or when more than one hypoglycemic drug is used.