

13522 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

a. Impairment of renal function increases the risk of lactic acidosis. Renal function tests, such as serum creatinine, should be performed prior to phenformin therapy and at least annually thereafter. Phenformin should not be used in patients with impaired renal function, e.g., serum creatinine over 1.5 milligrams/100 milliliters, except in extraordinary circumstances.

b. Cardiovascular collapse (shock), congestive heart failure, acute myocardial infarction and other conditions characterized by hypoxemia have been associated with lactic acidosis and also may cause prerenal azotemia. Use of phenformin in patients particularly prone to develop such conditions must be carefully considered and the risks weighed against possible benefits. When such events occur in patients on phenformin therapy, the drug should be discontinued promptly.

c. Gastrointestinal disturbances are the most common adverse reactions to phenformin therapy. These symptoms must be distinguished from the symptoms of developing lactic acidosis. Anorexia