

13516 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(c) Labeling for oral hypoglycemic drugs of the biguanide category shall be as follows:

DESCRIPTION

(Trade name, established name) is an oral blood-glucose-lowering drug of the biguanide category. It is a white, crystalline, water-soluble compound, formulated as (to be supplied by firm) for oral administration. (Manufacturer to add structural formula and other appropriate information).

ACTIONS

The mechanism of action of phenformin is not established but its ability to cause increased peripheral glucose uptake in vitro appears to be related to its inhibition of cellular oxidative processes. It does not stimulate insulin production. Many patients who at first demonstrate an adequate glucose-lowering effect with (drug) subsequently prove to be no longer satisfactorily responsive, i.e., secondary failure may occur.