

We are investigating all possible aspects of this problem. If you have any direct knowledge of a hypertensive episode, a cerebrovascular accident or other untoward reaction associated with Parnate (tranylcypromine, SK&F) therapy, we would appreciate your sending a complete description to our Medical Department or to the FDA. If possible, case reports should include a detailed statement of the patient's medical history and a listing of the foods and other drugs ingested immediately preceding the onset of acute symptoms. We will provide all physicians with a further report on this subject as soon as definitive information is available.

Very sincerely,

WALTER A. MUNNS,
President.

PFIZER LABORATORIES,
New York, N.Y., August 21, 1963.

IMPORTANT DRUG WARNING PLEASE READ

DEAR DOCTOR: It has come to our attention recently that Diabinese® (chlorpropamide) is being used in some instances for the treatment of diabetes during pregnancy. Sulfonyleurea therapy of diabetes during pregnancy is contrary to the advice and recommendations of the general consensus of expert opinion on the subject, and there is, therefore, insufficient data supporting its efficacy and safety in this condition.

Pregnancy, along with infection, surgery, trauma and other stressful situations has always been considered to be a complication of diabetes and an indication for insulin therapy. It is almost axiomatic that diabetic control becomes more complicated and insulin requirements increase under such conditions.

The primary indication for sulfonyleurea therapy is uncomplicated diabetes mellitus of the stable, mild or moderately severe, non-ketotic, maturity-onset type. Accordingly, the use of this drug in pregnancy is not indicated. In addition, diabetes in the majority of women capable of bearing children is not of the stable, maturity-onset type.

We are unaware of significant reliable data on the use of chlorpropamide during pregnancy, and therefore, its use is contraindicated in this condition. Indeed, caution is urged in prescribing this drug to any woman capable of bearing children because of the potential danger to the mother and to the embryo or fetus in an unsuspected pregnancy.

Accordingly in cooperation with the Food and Drug Administration, we have revised our Diabinese (chlorpropamide) package insert to include the following caution:

"Diabinese (chlorpropamide) is contraindicated in pregnancy. In view of the question of safety in this condition, serious consideration should be given to the potential hazard of its use in women of the childbearing age who may become pregnant."

In closing, we urge that any reports of your past experience with Diabinese (chlorpropamide) during pregnancy, either adverse or favorable, be forwarded in detail to us and to the Food and Drug Administration. We shall hold such reports in strict confidence.

Very truly yours,

ROBERTS M. REES, M.D.,
Medical Director.

LLOYD BROTHERS, INC.,
Cincinnati, Ohio., August 6, 1963.

DEAR DOCTOR: We would like to call to your attention a mystery and possible problem which has been encountered with our new product Copoietin Ferrous Tablets. Copoietin Ferrous was introduced eight weeks ago after several years of clinical research. The results convinced us that we had a quality product to offer for the treatment of anemia.

During the past week, we have discovered that some tablets of Copoietin Ferrous do not disintegrate properly in the body although every batch has passed the rigid table disintegration tests as established by U.S.P. For some as yet unexplained reason, the accepted standard disintegration tests do not enable us to assure Lloyd Brothers' standards of quality. Until this mystery can be solved, Lloyd Brothers has elected to withdraw from distribution all stocks of the drug presently available for sale. We ask that you destroy any samples