

3139a COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

"one of a series". In order to avoid any misunderstanding, we have discontinued the use of these "Miltown" advertisements as well as the described "Deprol" advertisement.

Sincerely,

WALLACE PHARMACEUTICALS.

ROCHE LABORATORIES,
Nutley, N.J.,

DEAR DOCTOR: At the request of the Food and Drug Administration, we are extending the "brief summary" of prescribing information for Librium® (Chlordiazepoxide HCl) which appears in medical journal advertisements by adding several phrases and items from the unchanged official package circular.

The revised "brief summary" for medical journals is attached, indicating by capitalization the requested added material. Prescribing information in all Librium (chlordiazepoxide HCl) package circulars, direct mail information and brochures is complete and requires *no* change. The safety and effectiveness of the product are *not in question*.

In addition, in future medical journal advertisements for Librium (chlordiazepoxide HCl) in geriatric patients, we are amplifying statements which have appeared concerning possible side effects and initial dosage:

The statement that "Side effects in most instances are mild in degree and readily reversible with reduction of dosage," will be extended by the observations made in our package circular which point out that drowsiness, ataxia and confusion have been reported in some patients, particularly the elderly and debilitated, occasionally at lower dosage ranges, and that in a few instances syncope has been reported.

Whereas in geriatrics, the *usual daily dosage* is 5 mg, two to four times daily, the *initial dosage* in elderly and debilitated patients should be limited to 10 mg or less per day, adjusting as needed and tolerated.

We hope the additional detail in medical journal advertising clarifies the use of the product in accordance with the enclosed package circular.

Sincerely,

ROBERT E. DIXON, M.D.
Director, Professional Services.

(NOTE.—This revised "brief summary" for use in future medical journal advertising contains additional phrases and items (printed in capital letters) from the official package circular which remains unchanged.)

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR LIBRIUM® (CHLORDIAZEPOXIDE HCl)

Before prescribing, please consult complete product information, a summary of which follows:

Contraindications: Patients with known hypersensitivity to the drug.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. AS WITH ALL CNS-ACTING DRUGS, CAUTION PATIENTS against hazardous occupations requiring complete mental alertness (E.G., OPERATING MACHINERY, DRIVING). THOUGH PHYSICAL AND PSYCHOLOGICAL DEPENDENCE HAVE RARELY BEEN REPORTED ON RECOMMENDED DOSES, use caution in administering to addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in pregnancy, lactation, or in women of childbearing age requires that its potential benefits be weighed against its possible hazards.

Precautions: In the elderly and debilitated, and in children over SIX, limit to smallest effective dosage (INITIALLY 10 MG OR LESS PER DAY) TO PRECLUDE ATAXIA OR OVERSEDATION, increasing gradually as needed and tolerated. NOT RECOMMENDED IN CHILDREN UNDER SIX. THOUGH GENERALLY NOT RECOMMENDED, IF COMBINATION THERAPY WITH OTHER PSYCHOTROPICS SEEMS INDICATED, CAREFULLY CONSIDER INDIVIDUAL PHARMACOLOGIC EFFECTS, PARTICULARLY IN USE OF POTENTIATING DRUGS SUCH AS MAO INHIBITORS AND PHENOTHIAZINES. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions, E.G., EXCITEMENT STIMULATION AND ACUTE RAGE) have been reported in psychiatric patients and hyperactive aggressive