

was 2.0 per 100 woman-years. The rate of 0.2 used in the ad included only those patients who insisted that they had adhered to the regimen.

QUESTRAN®

The FDA considers the summary of warning information in the journal advertisement for Questran to be inadequate in that it did not contain any information on precautions and warnings. We have attached a revised "Brief Summary," which contains the omitted precautions and warning information in capital letters.

We are discontinuing the ads in question, and future advertising will incorporate the above corrections. The safety and effectiveness of Oracon and Questran are not in question when the drugs are used in accordance with the official package inserts.

Sincerely,

P. A. WALTER, M.D., *Director, Medical Research Department.*

BRIEF SUMMARY OF WARNING INFORMATION FOR QUESTRAN®
(CHOLESTYRAMINE)

(NOTE.—This revised "Brief Summary," for use in medical journal advertising, contains additional information, in capital letters, taken from the official package insert.)

Indication.—Questran relieves pruritus associated with partial biliary obstruction.

Contraindication.—Patients with complete biliary obstruction.

WARNING.—ALWAYS ADMIX QUESTRAN WITH WATER OR OTHER FLUIDS BEFORE INGESTING. TO PREVENT DEFICIENCIES OF VITAMINS A, D AND K, SUPPLEMENT THE DIET, AND SEE PRECAUTIONS BELOW.

USAGE IN PREGNANCY.—THE SAFE USE OF QUESTRAN BY PREGNANT AND LACTATING WOMEN HAS NOT BEEN ESTABLISHED.

PRECAUTIONS.—WITH PROLONGED QUESTRAN ADMINISTRATION, GIVE VITAMINS A AND D DAILY. INCREASED BLEEDING TENDENCIES MAY DEVELOP. PROMPT RESPONSE TO PARENTERAL VITAMIN K, MAY BE ANTICIPATED. ADMINISTER CHLOROTHIAZIDE, PHENYLBUTAZONE OR WARFARIN ONE HOUR BEFORE QUESTRAN. AS A PRECAUTIONARY MEASURE, ADMINISTER ALL OTHER DRUGS 30 MINUTES TO 1 HOUR BEFORE QUESTRAN. A THEORETICAL POSSIBILITY EXISTS THAT PROLONGED USE MAY LEAD TO DEVELOPMENT OF HYPERCHOLEMIC ACIDOSIS. THERE IS NO ESTABLISHED RATIONALE FOR USE OF QUESTRAN IN THE RELIEF OF PRURITUS ASSOCIATED WITH OTHER DISEASE PROCESSES.

ADVERSE REACTIONS

Gastrointestinal and Dermatological.—Constipation, diarrhea, nausea, gastrointestinal distress, and vomiting have been reported by about 20% of patients using cholestyramine. Reported less frequently were ABDOMINAL PAIN AND DISTENTION, rash, irritation of the skin, tongue and perianal area.

Bleeding.—In 1% of patients, increased bleeding tendencies occurred due to hypoprothrombinemia.

Steatorrhea.—Steatorrhea occurred but rarely, and then on doses in excess of 24 grams per day.

Cholesterol.—In patients with pruritus associated with partial biliary obstruction, serum cholesterol levels usually decrease during Questran therapy. (Clinical experience has not established the therapeutic use of Questran to reduce serum cholesterol.)

Biliary Calcification.—Two possible instances have been observed, but a casual relationship has not been established.

GEIGY PHARMACEUTICALS,
DIVISION OF GEIGY CHEMICAL CORP.,
Ardley, N.Y.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to recent journal advertisements for our products (Hygroton® and Regroton®) which the FDA considers to be misleading.