ERING EFFECT IS OBSERVED. Withdrawal is indicated if iodism or new cardiac signs or symptoms develop.

*ADVERSE REACTIONS:* For the most part due to metabolism, AND THUS MORE COMMON IN THE HYPOTHYROID PATIENT, ESPECIALLY THE HYPOTHYROID CARDIAC. Cardiac changes have rarely been precipitated in non-cardiac patients. Angina pectoris (0.2% incidence), arrhythmia (0.5%), MYOCARDIAL ISCHEMIA (<0.1%), CARDIOMEGALY (<0.1%), FATAL AND NON-FATAL myocardial infarctions (<0.2%). Insomnia, nervousness, palpitations, tremors, WEIGHT LOSS, LID LAG, SWEATING, FLUSHING, HYPERTHERMIA, HAIR LOSS, CHANGES IN BOWEL HABITS, DIURESIS, AND MENSTRUAL IRREGULARITIES MAY ALSO BE RELATED TO THE MILD METABOLIC ACTION. A FEW PATIENTS DEVELOPED ITCHING AND SKIN RASHES, APPARENTLY FROM IODISM.

DYSPEPSIA, NAUSEA AND VOMITING, AND CHANGES IN APPETITE OCCURRED IN LESS THAN 1%. HEADACHE, CHANGES IN LIBIDO, HOARSENESS, TINNITUS, DIZZINESS, PERIPHERAL EDEMA, MALAISE, TIREDNESS, VISUAL DISTURBANCES, PSYCHIC CHANGES, PARESTHESIA, MUSCLE PAIN, AND BIZARRE COMPLAINTS WERE REPORTED IN LESS THAN 1% OF TREATED PATIENTS. GALLSTONES WERE NEWLY DISCOVERED IN 13 PATIENTS, AND CHOLESTATIC JAUNDICE IN ONE, ALTHOUGH RELATIONSHIP TO DRUG THERAPY WAS NOT ESTABLISHED. IN A TOTAL OF 19 PATIENTS, PRE-EXISTING PERIPHERAL VASCULAR DISEASE, EXOPHTHALMOS, RETINOPATHY, AND DISTURBED SENSORIUM CONTINUED TO WORSEN, CEREBROVASCULAR ACCIDENTS, THROMBOPHLEBITIS, AND G.I. HEMORRHAGES EACH OCCURRED IN LESS THAN 1% OF PATIENTS, BUT THERE APPEARS TO BE NO RELATIONSHIP TO DEXTROTHYROXINE THERAPY.

In the nearly 3,000 patients studied, the withdrawal rate was less than 3%.

*PHARMACOLOGY:* MOST EVIDENCE INDICATES THE MECHANISM OF ACTION IS TO STIMULATE THE LIVER TO INCREASE CATABOLISM OF CHOLESTEROL; SYNTHESIS OF CHOLESTEROL IS NOT INHIBITED, AND ABNORMAL METABOLIC END PRODUCTS DO NOT ACCUMULATE IN THE BLOOD.

*DOSAGE RECOMMENDATIONS:* Dosage should start at 1.0 or 2.0 mg. daily to be increased monthly in 1.0 or 2.0 mg. increments to a maximum of 6.0 to 8.0 mg. daily if necessary for control of serumcholesterol in the adult. In hypothyroid patients, the more conservative dosage schedule should be observed. Pediatric dosage is 0.05 mg./kg. daily, increased monthly in 0.05 mg./kg. increments to 0.1 mg./kg. or 4.0 mg. daily if necessary for control.

*SUPPLIED:* 2.0 mg. and 4.0 mg. scored tablets in prescription bottles of 30.

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MEAD JOHNSON LABORATORIES,
*Evansville, Ind., June 30, 1967.*

DEAR DOCTOR: The Food and Drug Administration has requested that we call your attention to current medical journal advertisements for Oracon and Questran which the FDA regards as misleading.

ORACON®

The ad claims that the drug provides ". . . oral contraception with effects which closely parallel those of the natural hormonal cycle" and also contains a related slogan implying such effects are "So Close to Nature." The FDA points out that not nearly all effects of oral contraceptives parallel those of the natural hormonal cycle and that some of the effects of these drugs are of profound or undetermined nature.

The ad emphasizes the low incidence of certain less serious side effects such as amenorrhea, breakthrough bleeding, weight gain, etc. However, it fails to give adequate emphasis to more serious known side effects—or adequate emphasis to the possible occurrence of thrombophlebitis, pulmonary embolism or cerebral vascular accident.

The FDA points out that the pregnancy rates claimed in the ad were incorrectly based on 1065 women instead of only 880, and that the ad improperly features a pregnancy rate of 0.2 per 100 woman-years. While available data do not provide a reliable scientific basis for a statement of true pregnancy rates, experience reported to us shows that the unadjusted rate for all women who were given Oracon