when calculated according to Clark's rule or Young's rule. In order to minimize the possibility of toxic reactions in children use of the 1% concentration of Citanest (prilocaine) hydrochloride is recommended.

Patients with Liver Disease and Debilitated Patients: The use of any general or local anesthetic agent is undesirable in patients with liver disease or severely debilitated patients. However, for emergency or definitive surgical procedures where a local anesthetic is required, care should be taken to use the lowest dose and concentration of Citanest (prilocaine) hydrochloride necessary to provide adequate anesthesia. It is extremely difficult to recommend a maximum safe dose of any drug for such patients, since this will depend on the degree of liver damage and degree of debilitation. For most anesthetic procedures, it is advisable to use the 1% concentration of Citanest (prilocaine) hydrochloride in order to obtain the minimum dose that will provide adequate anesthesia and thereby avoid possible toxic reactions in patients with liver disease or debilitated patients. In such patients it is probably not advisable to exceed a maximum dose of 400 mg.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to certain advertisements for Mysteclin–F products which the FDA regards as misleading. The main theme of the advertising, which we have stopped, suggests that "almost every candidate for broad-spectrum antibiotic therapy, is a candidate for Mysteclin–F."

We wish to emphasize that those patients selected for tetracycline therapy who are known to be particularly susceptible to candidal superinfection are the potential candidates for Mysteclin–F therapy.

The FDA points out that recent journal advertisements for these products suggested that candidal superinfection is a serious problem with the use of ampicillin. This was not supported by the reference used in the ads. Although the reference cited included the statement that candidal overgrowth may follow ampicillin therapy, the FDA has asked that we point out that the significance of this overgrowth has not been established.

Further, the same ads omitted important warning information relating to precautions and side effects. The nature and extent of the omission are capitalized in the enclosed "Brief Summary".

Sincerely,

SQUIBB.

(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 insert.)

Contraindications: History of hypersensitivity to either component.

Warning: If renal impairment exists, lower-than-usual doses are indicated to avoid systemic accumulation and possible liver toxicity; on prolonged use, tetracycline serum level determinations may be advisable. Photodynamic reactions, although rare with teracycline, may occur; if they occur, discontinue drug. Advise photosensitive patients to avoid direct sunlight.

Precautions: Watch for signs of secondary infection due to nonsusceptible organisms; discontinue drug and/or institute appropriate therapy if this occurs. SUPERINFECTION OF THE BOWEL BY STAPHYLOCOCCI MAY BE LIFE-THREATENING. Use of tetracycline, particularly long-term use, BUT ALSO IN USUAL SHORT TREATMENT COURSES, during the LATTER HALF OF GESTATION, NEONATAL PERIOD, AND EARLY CHILDHOOD tooth development may cause discoloration of teeth. TETRACYCLINE MAY FORM A STABLE CALCIUM COMPLEX IN BONE-FORMING TISSUE WITHOUT HARMFUL EFFECTS REPORTED THUS FAR. During long-term therapy, perform periodic renal, hepatic, and hematopoietic function studies. Increased intracranial pressure with bulging fontanels has been observed rarely in infants taking therapeutic doses of tetracycline. USE WITH CAUTION IN PERSONS WITH A HISTORY OF ALLERGY, ASTHMA, HAY FEVER, OR URTICARIA DUE TO GREATER POSSIBILITY OF SENSITIVITY REACTIONS. CROSS-SENSITIZATION WITH OTHER TETRACYCLINES IS COMMON. IN THE TREATMENT OF GONORRHEA, PATIENTS WITH A SUSPECTED LESION OF SYPHILIS SHOULD HAVE DARK-FIELD EXAMINATIONS BEFORE RECEIVING TETRACYCLINE AND MONTHLY SEROLOGIC TESTS FOR A MINIMUM OF THREE MONTHS.