

Novobiocin Preparations For Oral and Parenteral Use

DRUGS FOR HUMAN USE—DRUG EFFICACY STUDY IMPLEMENTATION

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following oral and parenteral forms of novobiocin:

1a. Albamycin Mix-O-Vial, Power for Injection; 500 milligrams of novobiocin, as sodium novobiocin, per vial;

b. Albamycin Capsules; 250 milligrams of novobiocin, as sodium novobiocin, per capsule;

c. Albamycin Syrup; 125 milligrams of novobiocin, as calcium novobiocin, per 5 cubic centimeters; all marketed by the Upjohn Co., 301 Henrietta Street, Kalamazoo, Mich. 49001.

2. Cathomycin Sodium Capsules; 250 milligrams of novobiocin, as novobiocin sodium, per capsule; marketed by Merck & Co., Inc., Rahway, N.J. 07065.

The Food and Drug Administration has concluded that novobiocin is effective for certain indications and is appropriate for use under the qualifications stated herein.

Preparations containing novobiocin are subject to certification pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act. Batches of the drug for oral or parenteral use for which certification is requested should provide for labeling information in accord with labeling guidelines developed on the basis of this reevaluation of the drug and published in this announcement. The holders of antibiotic forms 5 or 6 approved for a drug of the kind described above are requested to submit, within 30 days after publication hereof in the Federal Register, supplements to their antibiotic form 5 or 6 applications to provide for revised labeling. Those parts of the labeling indicated below should be substantially as follows (optional additional information, applicable to the drug, may be proposed under other appropriate paragraph headings and should follow the information set forth below):

"NOVOBIOCIN

"WARNING

"Novobiocin Should be Used Only for Those Serious Infections Where Other Less Toxic Drugs Are Ineffective or Contraindicated, Because of the Following:

"1. The High Frequency of Adverse Reactions, Including Hepatic Dysfunction, Blood Dyscrasias, and Rashes.

"2. The Rapid and Frequent Emergence of Resistant Strains, Especially Staphylococci.

"3. Its Spectrum of Antibacterial Activity Is Covered by Several Other Safer and More Effective Drugs.

"DESCRIPTION

"(Descriptive information to be included by the manufacturer or distributor should be confined to an appropriate description of the physical and chemical properties of the drug and the formulation.)

"ACTIONS

"In vitro novobiocin shows activity against *Staphylococcus aureus* and against some strains of *Proteus vulgaris*. It shows no cross-resistance with penicillin against resistant strains of *M. pyogenes* var. *aureus* (*Staphylococcus aureus*); however, in vitro studies indicate that *M. pyogenes* var. *aureus* very rapidly develops resistance to novobiocin.

"INDICATIONS

"Novobiocin is indicated only for the treatment of serious infections due to susceptible strains of *Staphylococcus aureus* when the patient is sensitive or there is other contraindication to other effective antibiotics, such as the penicillins, cephalosporins, vancomycin, lincomycin, erythromycin, and the tetracyclines.