

To clarify further the status of this drug in the therapy of infectious disease, the indications for use have been stated in the recently revised labeling as follows:

INDICATIONS: IN ACCORD WITH THE CONCEPTS IN THE "WARNING BOX" AND THIS INDICATIONS SECTION, CHLORAMPHENICOL MUST BE USED ONLY IN THOSE SERIOUS INFECTIONS FOR WHICH LESS POTENTIALLY DANGEROUS DRUGS ARE INEFFECTIVE OR CONTRA-INDICATED. HOWEVER CHLORAMPHENICOL MAY BE CHOSEN TO INITIATE ANTIBIOTIC THERAPY ON THE CLINICAL IMPRESSION THAT ONE OF THE CONDITIONS BELOW IS BELIEVED TO BE PRESENT; IN VITRO SENSITIVITY TESTS SHOULD BE PERFORMED CONCURRENTLY SO THAT THE DRUG MAY BE DISCONTINUED AS SOON AS POSSIBLE IF LESS POTENTIALLY DANGEROUS AGENTS ARE INDICATED BY SUCH TESTS. THE DECISION TO CONTINUE USE OF CHLORAMPHENICOL RATHER THAN ANOTHER ANTIBIOTIC WHEN BOTH ARE SUGGESTED BY IN VITRO STUDIES TO BE EFFECTIVE AGAINST A SPECIFIC PATHOGEN SHOULD BE BASED UPON SEVERITY OF THE INFECTION, SUSCEPTIBILITY OF THE PATHOGEN TO THE VARIOUS ANTIMICROBIAL DRUGS, EFFICACY OF THE VARIOUS DRUGS IN THE INFECTION, AND THE IMPORTANT ADDITIONAL CONCEPTS CONTAINED IN THE "WARNING BOX" ABOVE:

1. ACUTE INFECTIONS CAUSED BY SUSCEPTIBLE STRAINS OF *SALMONELLA TYPHI*

Chloramphenicol is a drug of choice.* It is not recommended for the routine treatment of the typhoid "carrier state".

2. SERIOUS INFECTIONS CAUSED BY SUSCEPTIBLE STRAINS IN ACCORDANCE WITH THE CONCEPTS EXPRESSED ABOVE:

- a. *Salmonella* species
- b. *H. influenzae*, specifically meningococcal infections
- c. Rickettsia
- d. Lymphogranuloma-psittacosis group
- e. Various gram-negative bacteria causing bacteremia, meningitis or other serious gram-negative infections
- f. Other susceptible organisms which have been demonstrated to be resistant to all other appropriate anti-microbial agents.

3. CYSTIC FIBROSIS REGIMENS

* In the treatment of typhoid fever some authorities recommend that chloramphenicol be administered at therapeutic levels for 8-10 days after the patient has become afebrile to lessen the possibility of relapse.

The revised labeling suggests that patients being treated with chloramphenicol be hospitalized where indicated to facilitate observation during therapy. It also includes cautionary information regarding use in pregnancy and lactation, and the listing of leukemia as an additional adverse reaction. An estimate of the incidence of fatal aplastic anemia is included based on a report to the California State Assembly and Senate by the California Medical Association and State Department of Public Health, January 1, 1967.