

may be indicated in certain severe respiratory infections

Because of its wide antibacterial spectrum and its ability to diffuse into infective foci, CHLOROMYCETIN may be of value in the treatment of selected severe respiratory tract infections due to susceptible microorganisms. However, as with any antibacterial agent, the administration of CHLOROMYCETIN must be adjunctive to the overall therapeutic approach to this family of diseases. Appropriately treated, good results can be expected in bacterial pneumonia and empyema; in bacterial complications of bronchiectasis and bronchitis, all of which are severe disorders often chronic and difficult to eradicate.

The decision to choose CHLOROMYCETIN from among a group of antibiotics suggested by *in vitro* studies to be potentially effective against a specific respiratory tract pathogen(s) should be guided by severity of infection, relative susceptibility of the pathogen(s) to the various antibacterial drugs, relative efficacy of the various drugs in this family of infections, and the important additional concepts contained in the "warning box."

Patients with respiratory tract infections usually become afebrile in 18 to 72 hours on recommended doses; roentgenographic clearing may be slower.

Neoplastic, fungal, and mycobacterial disease as a cause of persistent respiratory disease should be ruled out by appropriate means.



Chloromycetin

Detailed information, including indications and dosage, appears in the package inserts of CHLOROMYCETIN products for systemic use. Consult the appropriate package insert.

Warning: Serious and even fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, granulocytopenia) are known to occur after the administration of chloramphenicol. Blood dyscrasias have occurred after both short-term and prolonged therapy with this drug. Bearing in mind the possibility that such reactions may occur, chloramphenicol should be used only for serious infections caused by organisms which are susceptible to its antibacterial effects. Chloramphenicol should not be used when other less potentially dangerous agents will be effective. It must not be used in the treatment of trivial infections such as colds, influenza, or infections of the throat; or as a prophylactic agent to prevent bacterial infections.

Precautions: It is essential that adequate blood studies be made during treatment with the drug. While blood studies may detect early peripheral blood changes such as leukopenia or granulocytopenia, before they become irreversible, such studies cannot be relied on to detect bone marrow depression prior to development of aplastic anemia.

CHLOROMYCETIN, an antibiotic having therapeutic activity against a wide variety of organisms, must, in accordance with the concepts in the "warning box" above, be used only in certain severe infections.

Contraindications: Chloramphenicol is contraindicated in individuals with a history of previous sensitivity reaction to it.

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Precautions and Side Effects: Untoward reactions in man are infrequent; however, they have been reported with both short-term and prolonged administration of the drug. Among the reactions reported are blood dyscrasias as mentioned in the warning. When, during the course of therapy, blood counts show unusual deviations which may be attributable to the drug such as reticulocytopenia, leukopenia, or thrombocytopenia, therapy with chloramphenicol should be discontinued. Also reported are certain gastrointestinal reactions resulting in glossitis and stomatitis, which are indications to stop the drug. On rare occasions, superimposed infection by *Candida albicans* may produce widespread oral lesions of the thrush type. Diarrhea and irritation of perianal tissues have been reported. Pseudomembranous enterocolitis has been reported in a few patients. Hypersensitivity reactions manifested by angioneurotic edema and vesicular and maculopapular types of dermatitis have been reported in chloramphenicol-sensitive patients. Urticaria and vesicular lesions have been observed. They are usually mild in character and ordinarily subside promptly upon cessation of treatment. Febrile reactions have been reported.

A reaction of the Jarisch-Herxheimer type has been reported following therapy in syphilis, brucellosis, and typhoid fever. Typhoid fever patients have exhibited a "shock-type reaction" characterized by circulatory collapse attributed to sudden release of endotoxin. Neurotoxic reactions, including optic and peripheral neuritis, headache, mild depression, "dazed feelings," internal ophthalmoplegia, mental confusion, and delirium have been reported. Symptoms of peripheral neuritis or decreased visual acuity call for prompt withdrawal of the antibiotic and the possible use of large doses of oral or parenteral vitamin B complex. When prolonged high dosage is necessary, toxic side effects may occur which call for dosage reduction or discontinuance of chloramphenicol therapy. Adults and children with impaired liver or kidney function, or both, may retain excessive amounts of the drug. In such instances, dosages should be adjusted accordingly.

Toxic reactions, the signs and symptoms of which have been referred to as the "gray syndrome," with some fatalities, have resulted from high concentrations of the drug in the premature and newborn age groups. One case of "gray syndrome" has been reported in an infant born to a mother having received chloramphenicol during labor. The following summarizes the clinical and laboratory studies that have been made on these patients: (1) In most cases therapy with chloramphenicol had been instituted within the first 48 hours of life. (2) Symptoms first appeared after 3 to 4 days of continued treatment with high doses of chloramphenicol. (3) The symptoms appeared in the following order: (a) abdominal distention with or without emesis; (b) progressive pallid cyanosis; (c) vasomotor collapse, frequently accompanied by irregular respiration; and (d) death within a few hours of onset of these symptoms. (4) The progression of symptoms from onset to exitus was accelerated with higher dose schedules. (5) Preliminary blood serum level studies revealed unusually high concentrations of chloramphenicol after repeated doses. (6) Termination of therapy upon early evidence of the associated symptomatology frequently reversed the process with complete recovery.

Precautions: See "warning box" for precautions.

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient is essential. If new infections caused by nonsusceptible organisms appear during therapy, the drug should be discontinued and appropriate measures should be taken.

Monitoring of liver and kidney function should be accomplished during therapy in patients with existing liver or kidney disease.

Supplied: CHLOROMYCETIN is available in a variety of forms including Kapsels* of 250 mg.

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