

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15517

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CHLOROMYCETIN

Chloromycetin (chloramphenicol Parke-Davis) is a crystalized antibiotic with therapeutic activity against a great variety of pathogenic micro-organisms.

Chloromycetin is absorbed very well when administered orally and quickly gives effective concentrations in the fluids and tissues of the organism.

DOSAGE AND ADMINISTRATION

Generally a dose of 50 mg/kg/day is recommended, divided in four doses administered at intervals of 6 hours. In exceptional cases, such as infections caused by moderately resistant micro-organisms, or in serious infections like septicemia and meningitis, the dose can be increased to 100 mg/kg/day. However, this higher dose should be reduced as soon as it is possible and by the physician's criterion.

In cases of hepatic or renal insufficiency, when the capacity to metabolize or to excrete the chloramphenicol can be reduced, the physician should adjust the dose accordingly. In case of doubt and if laboratories are available for tests, the serum concentration of chloramphenicol can be verified by analytic methods.

Premature infants, newborn infants and other children with physiological immaturity. (See "Gray Syndrome" under Adverse Reactions).

In general, a dose of 25 mg/kg/day divided in four doses administered at intervals of 6 hours produces and maintains chloramphenicol concentrations in blood and tissues adequate to control the majority of infections in premature infants, newborn infants and others with physiological immaturity. Generally after the first two weeks of life full-term infants can tolerate a maximum dose of 50 mg/kg/day, divided in 4 doses administered at intervals of 6 hours. In case of doubt, serum chloramphenicol concentrations should be verified by analytical methods.

Because of reasons mentioned hereinafter (see "Gray syndrome") these doses should not be normally exceeded.

CLINICAL INDICATIONS

Clinical use has established that chloramphenicol (Chloromycetin Parke-Davis) is an antibiotic of great efficacy against an extensive variety of bacterial infections by rickettsial and lymphogranuloma-psittacosis micro-organisms.

It has a great anti-microbial activity and diffuses rapidly throughout tissues and body fluids, including the cerebro-spinal fluid. Chloramphenicol is a potent therapeutic agent which should not be used for trivial infections. It should be administered according to the instructions of a physician.

Chloramphenicol should be considered by the physician for the treatment of bacteroides infections, infections by rickettsias and lymphogranuloma-psittacosis. His decision should be based on the antibiotic spectrum, on the general clinical condition and the possible risk which is involved.

Chloromycetin is indicated specifically for bacterial meningitis, typhoid fever, septicemia due to gram-negative organisms and other serious infections where the bacteriological evidence or the clinical judgment indicate that Chloromycetin is the appropriate antibiotic.

Experience has demonstrated the value of chloramphenicol in the treatment of infectious conditions in ophthalmology, otology and dermatology.