

15496 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

2. Parke Davis Chloromycetin labels in Spain acquired in 1969-1973.

Purchased in Madrid, Spain

On October 29, 1969

To the Medical Profession:

(old label - pre 1973 new label - Chloromycetin Monograph)

CHLOROMYCETIN (*)

(*) Registered trademark.

Chloromycetin (chloramphenicol, P. D. and Co.) is a crystallized antibiotic with specific 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

In general, clinical experience with Chloromycetin in acute and chronic infections of adults indicates that the majority respond rapidly to an oral ^{dose} ~~dosage~~ of 50 mg per kilo weight per day, administered fractionally over several days or until the signs and symptoms of the infection have been brought under control. When the temperature becomes normal, a ^{dose} ~~dosage~~ of 25 mg per kilo weight per day, administered fractionally, is generally sufficient. On the basis of an analysis of the dosage used in adults, it has been established that a total dose of Chloromycetin ranging between 10 and 15 g is sufficient in the ~~max~~ majority of acute infections. It may be necessary to give 15 g or more in chronic infections. The interval between doses should never be greater than 6 hours, in order that the concentration of Chloromycetin in the blood may never drop below the minimal effective concentration.

In the majority of infections, the dosage of Chloromycetin for infants and children at the beginning of therapy is calculated at between 50 and 100 mg per kilo weight per day, administered fractionally at 4-to-6-hour intervals. In a severe infection, 75 to 100 mg per kilo weight per day may be given at the beginning of the therapy. A dosage of 30 to 50 mg per kilo weight is