

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15561

17. Centra Nacional de Farmacobiología (CNDF's new statements on chloramphenicol used as a basis for new labeling of chloramphenicol products of Parke-Davis and other companies in Spain.

Received from:
Centro Nacional De Farmacobiología
(Control of Medicines) (basis for labeling chloramphenicol medicines)
Madrid, Spain
Sep. 27, 1973
CHLORAMPHENICOL
Specific indications

- 1°. Acute infections caused by Salmonella Typhi (it is not indicated for treatment of the bearers).
- 2°. Acute infections caused by diverse salmonellas, H influenzae (specifically in meningitis infections), Rickettsias of the lymphogranuloma-psittacosis group, Gram negative bacteria causing meningitis or bacteremia and, finally, other organisms (sensitive) resistant to all the rest of the anti-microbial agents.

Dosification: To the proper indication of the specialty, the following paragraph should be added:

"The daily dose for adults should not be over two grams, neither should be administered for more than ten days".

Secondary Effects:

After high dose and long treatments, chloramphenicol can give way to leukopenic, granulocytosis and anaemia, therefore it is very opportune to have hematic controls made during treatment.

In some cases it can also provoke neurological reactions of intolerance or hyperergias.

Counterindications:

Renal insufficiency and women in the first three months of gestation.

For newborns and premature babies doses over 25 mg/15 mg/kg/day are absolutely counter-indicated (respectively). The administration should be made via intramuscular and in one single dose.

CAUTION:

Its use should be reserved exclusively for the above mentioned indications.

See second statement - p. 3