

7. Zanders' comparison of new Spanish label with U.S. label.

The new Spanish label is a considerable improvement over the old Spanish label both in its indications for use and in its warnings of adverse effects. The new label states clearly - twice - that Chloromycetin should not be used for trivial infections and should be used under the instructions of a physician, the most important new statement which, coupled with the warning - twice - of blood dyscrasias including fatal aplastic anemia instead of the bland "changes in the blood following its use are rare" of the old label, should have a salutary effect in cutting down unnecessary use.

The new label also states that the decision to use Chloromycetin should be based on the antibiotic spectrum, the general clinical condition and the possible risk involved. This is much better than no general guidelines at all as in the old label but it is still weak compared to the U.S. label. The new label's indications for use are usually based on the micro-organisms or groups of micro-organisms involved instead of on sites of infections such as urinary tract infections and respiratory infections of the old label although it still includes infections in otology, ophthalmology, and dermatology. More importantly the specific indications for use are more similar to the more restricted U.S. label list. However, the Spanish label gives the physician the choice of basing his decision to use chloramphenicol on bacteriological evidence or clinical judgment while the U.S. label says sensitivity testing is essential.

The new label, after repeating that Chloromycetin should not be used for trivial infections and under the direction of a physician, warns that blood dyscrasias including aplastic anemia may be associated with administration of chloramphenicol and that blood studies should be repeated at appropriate intervals when possible especially during prolonged or intermittent treatment. The old label had only "Gray Syndrome" under Warning and under Tolerance just the "Chloromycetin is well tolerated and changes in the blood are rare" plus a similar blood study statement. The new label repeats both statements under Adverse Reactions, including there, however "aplastic anemia with fatalities". Again a distinct improvement over the old but lacking the strength and fullness of the U.S. warning and explanation.

The new label also includes other adverse effects: dryness of mouth, nausea, vomiting, sensitivity reactions, optical and peripheral neuritis, and warns to use lower dosage when given concurrently with anticoagulants and anticonvulsants and in cases of hepatic or renal insufficiency which the old label does not mention. Both labels treat the possibly fatal "Gray Syndrome" for premature and recently new born infants quite fully, far more so than the blood dyscrasias, in contrast to the U.S. label.

For more comments comparing the new Spanish label with the U.S. label, see "Comparison of the new German label with the old German label and the U.S. label." The new Spanish label and the new German label are very much alike being based on the same Monograph. However, the new Spanish label is perhaps a little better than the new German label in that it states, twice, that Chloromycetin should not be used for trivial infections and should be used under the direction of a physician in Indications as well as under Warning. The Spanish label also divides the diseases in which it should be used into those in which its use should be considered ~~and~~ by the physician and those in which it is specifically indicated.

The old German label was even worse than the Spanish old label in the tremendous number of indications for use and the comparison is stronger and in more detail but much of it applies to the Spanish labels.