

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10713

Recommended dosages are practical average figures which may require considerable modification as dictated by individual sensitivity or associated conditions. (See Warning Precautions.)

The average digitalizing dose with digoxin tablets is 1.25-1.5 milligrams. Digitalization may be accomplished by several approaches. A dose of 1.0 milligram orally usually produces a digitalis effect in 1-2 hours and becomes maximal in 6-8 hours. Additional doses of 0.25 or 0.5 milligram may be given at 6-8 hour intervals to full digitalization.

The usual daily oral maintenance dose is 0.25-0.5 milligram. For previously undigitalized patients, institution of daily maintenance therapy without a loading dose results in development of steady-state plateau concentrations in about seven days in patients with normal renal function. By giving 0.75 milligram digoxin daily in divided doses the desired therapeutic affect may be achieved in a previously undigitalized patient with normal renal function in 4-5 days.

It cannot be overemphasized that the values given are averages and substantial individual variation can be expected.

(If pediatric dosage is available the labeling sections above should be expanded to include the following information.)