Skip to main content

Digoxin Tablets (Digitek)

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In general, the adverse reactions of digoxin are dose-dependent and occur at doses higher than those needed to achieve a therapeutic effect. Hence, adverse reactions are less common when digoxin is used within the recommended dose range or therapeutic serum concentration range and when there is careful attention to concurrent medications and conditions.

Because some patients may be par ticularly susceptible to side effects with digoxin, the dosage of the drug should always be selected carefully and adjust- ed as the clinical condition of the patient warrants. In the past, when high doses of digoxin were used and little attention was paid to clinical status or concurrent medications, -adverse reactions to digoxin were more frequent and severe. Cardiac adverse reactions accounted for about one-half, gastrointestinal disturbances for about one fourth, and CNS and other toxicity for about one-four th of these adverse reactions. However, available evidence suggests that the incidence and severity of digoxin toxicit y has decreased substantially in recent years. In recent controlled clinical trials, in patients with predominantly mild to moderate heart failure, the incidence of adverse experiences was comparable in patients taking digoxin and in those taking placebo. In a large mortality trial, the incidence of hospitalization for suspected digoxin toxicity was 2% in patients taking digoxin compared to 0.9% in patients taking placebo. In this trial, the most common manifestations of digoxin toxicity included gastrointestinal and cardiac disturbances; CNS manifestations were less common.

Therapeutic doses of digoxin may cause heart block in patients with pre-existing sinoatrial or AV conduction disorders; heart block can be avoided***Cardiac:*** **Adults:** by adjusting the dose of digoxin. Prophylactic use of a cardiac pacemaker may be considered if the risk of heart block is considered unacceptable. High doses of digoxin may produce a variet y of rhy thm disturbances, such as first-degree, second-degree (Wenckebach), or third-degree heart block (including asystole); atrial tachycardia with block; AV dissociation; accelerated junctional (nodal) rhy thm; unifocal or multiform ventricular premature contractions (especially bigeminy or trigeminy); ventricular tachycardia; and ventricular fibrillation. Digoxin produces PR prolongation and ST segment depression which should not by themselves be considered digoxin toxicity. Cardiac toxicity can also occur at therapeutic doses in patients who have conditions which may alter their sensitivity to digoxin).**PRECAUTIONS** and**WARNINGS** (see

Digoxin may cause anorexia, nausea, vomiting and diarrhea. Rarely, the use of digoxin has been associated with abdominal pain, intestinal **Gastrointestinal:** ischemia, and hemorrhagic necrosis of the intestines.

Digoxin can produce visual disturbances (blurred or yellow vision), headache, weakness, dizziness, apathy, confusion and mental disturbances (such as **CNS:** anxiety, depression, delirium, and hallucination).

Gynecomastia has been occasionally observed following the prolonged use of digoxin. Thrombocytopenia and maculopapular rash and other skin reactions **Other:** have been rarely observed.

The following table summarizes the incidence of those adverse experiences listed above for patients treated with digoxin tablets or placebo from two randomized, double-blind, placebo-controlled withdrawal trials. Patients in these trials were also receiving diuretics with or without angiotensin-conver ting enzyme inhibitors. These patients have been stable on digoxin, and were randomized to digoxin or placebo. The results shown in Table 4 reflect the experience in patients following -dosage titration with the use of serum digoxin concentrations and careful follow-up. These adverse experiences are consistent with results from a large, placebo controlled mor talit y trial (DIG trial) wherein over half the patients were not receiving digoxin prior to enrollment.

Table 4: Adverse Experiences In Two Parallel, Double-Blind, Placebo-Controlled Withdrawal Trials (Number of Patients Reporting)

Placebo Patients (n=125)	Digoxin Patients (n=123)	Adverse Experience
		Cardiac
4	1	Palpitation
1	1	Ventricular extrasystole
1	2	Tachycardia
1	1	Heart arrest
		Gastrointestinal
4	1	Anorexia
2	4	Nausea
1	2	Vomiting
1	4	Diarrhea
6	0	Abdominal pain
		CNS

4	4	Headache
5	6	Dizziness
1	5	Mental disturbances
		Other
1	2	Rash
3	4	Death

Infants and Children: The side effects of digoxin in infants and children differ from those seen in adults in several respects. Although digoxin may produce anorexia, nausea, vomiting, diarrhea, and CNS disturbances in young patients, these are rarely the initial symptoms of overdosage. Rather, the earliest and most frequent manifestation of excessive dosing with digoxin in infants and children is the appearance of cardiac arrhy thmias, including sinus bradycardia. In children, the use of digoxin may produce any arrhythmia. The most common are conduction disturbances or supraventricular tachyarrhythmias, such as atrial tachycardia (with or without block) and junctional (nodal) tachycardia. Ventricular arrhythmias are less common. Sinus bradycardia may be a sign of impending digoxin intoxication, especially in infants, even in the absence of first degree heart block. Any arrhy thmia or alteration in cardiac conduction that develops in a child taking digoxin should be assumed to be caused by digoxin, until fur ther evaluation proves other wise.