Skip to main content

Disopyramide Phosphate (Norpace)

??? ??????: 30 ??????/?????? 2017

The adverse reactions which were reported in Nor-pace clinical trials encompass observations in 1,500 patients, including 90 patients studied for at least 4 years. The most serious adverse reactions are hypo-tension and congestive heart failure. The most common adverse reactions, which are dose dependent, are associated with the anticholinergic properties of the drug. These may be transitory, but may be persistent or can be severe. Urinary retention is the most serious anticholinergic effect.

The following reactions were reported in 10% to 40% of patients:

Anticholinergic: dry mouth (32%), urinary hesitancy (14%), constipation (11%)

The following reactions were reported in 3% to 9% of patients:

Anticholinergic: blurred vision, dry nose/eyes/ throat

Genitourinary: urinary retention, urinary frequency and urgency

Gastrointestinal: nausea, pain/bloating/gas

General: dizziness, general fatigue/muscle weakness, headache, malaise, aches/pains

The following reactions were reported in 1% to 3% of patients:

Genitourinary: impotence

Cardiovascular (see **WARNINGS**): hypotension with or without congestive heart failure, increased congestive heart failure (see **WARNINGS**), cardiac conduction disturbances, edema/weight gain, shortness of breath, syncope, chest pain

Gastrointestinal: anorexia, diarrhea, vomiting

Dermatologic: generalized rash/dermatoses, itching

Central nervous system: nervousness

Other: hypokalemia, elevated cholesterol/triglycerides

The following reactions were reported in less than 1%:

Depression, insomnia, dysuria, numbness/tingling, elevated liver enzymes, AV block, elevated BUN, elevated creatinine, decreased hemoglobin/hematocrit (see **WARNINGS**). Hypoglycemia has been reported in association with Norpace administration.

Infrequent occurrences of reversible cholestatic jaundice, fever, and respiratory difficulty have been reported in association with disopyramide therapy, as have rare instances of thrombocytopenia, reversible agranulocytosis, and gynecomastia. Some cases of LE (lupus erythematosus) symptoms have been reported; most cases occurred in patients who had been switched to disopyramide from procaina-mide following the development of LE symptoms. Rarely, acute psychosis has been reported following Norpace (disopyramide phosphate) therapy, with prompt return to normal mental status when therapy was stopped. The physician should be aware of these possible reactions and should discontinue Norpace (disopyramide phosphate) or Norpace (disopyramide phosphate) CR therapy promptly if they occur.