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Zantac (Ranitidine Hcl)

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The following have been reported as events in clinical trials or in the routine management of patients treated with ZANTAC (ranitidine hcl) . The relationship to therapy with ZANTAC (ranitidine hcl) has been unclear in many cases. Headache, sometimes severe, seems to be related to administration of ZANTAC (ranitidine hcl) .

Central Nervous System

Rarely, malaise, dizziness, somnolence, insomnia, and vertigo. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients. Rare cases of reversible blurred vision suggestive of a change in accommodation have been reported. Rare reports of reversible involuntary motor disturbances have been received.

Cardiovascular

-blockers, rare reports of arrhythmias such as tachycardia, bradycardia, atrioventricular block, and premature ventricular beats.$_2$As with other H

Gastrointestinal

Constipation, diarrhea, nausea/vomiting, abdominal discomfort/pain, and rare reports of pancreatitis.

Hepatic

There have been occasional reports of hepatocellular, cholestatic, or mixed hepatitis, with or without jaundice. In such circumstances, ranitidine should be immediately discontinued. These events are usually reversible, but in rare circumstances death has occurred. Rare cases of hepatic failure have also been reported. In normal volunteers, SGPT values were increased to at least twice the pretreatment levels in 6 of 12 subjects receiving 100 mg intravenously 4 times daily for 7 days, and in 4 of 24 subjects receiving 50 mg intravenously 4 times daily for 5 days.

Musculoskeletal

Rare reports of arthralgias and myalgias.

Hematologic

Blood count changes (leukopenia, granulocytopenia, and thrombocytopenia) have occurred in a few patients. These were usually reversible. Rare cases of agranulocytosis, pancytopenia, sometimes with marrow hypoplasia, and aplastic anemia and exceedingly rare cases of acquired immune hemolytic anemia have been reported.

Endocrine

-Controlled studies in animals and man have shown no stimulation of any pituitary hormone by ZANTAC (ranitidine hcl) and no antiandrogenic activity, and cimetidine induced gynecomastia and impotence in hypersecretory patients have resolved when ZANTAC (ranitidine hcl) has been substituted. However, occasional cases of impotence and loss of libido have been reported in male patients receiving ZANTAC (ranitidine hcl) , but the incidence did not differ from that in the general population. Rare cases of breast symptoms and conditions, including galactorrhea and gynecomastia, have been reported in both males and females.

Integumentary

Rash, including rare cases of erythema multiforme. Rare cases of alopecia and vasculitis.

Respiratory

RAs) compared to $_2$A large epidemiological study suggested an increased risk of developing pneumonia in current users of histamine-2-receptor antagonists (H RAs$_2$RA treatment, with an observed adjusted relative risk of 1.63 (95% CI, 1.072.48). However, a causal relationship between use of H$_2$patients who had stopped H and pneumonia has not been established.

Other

Rare cases of hypersensitivity reactions (e.g., bronchospasm, fever, rash, eosinophilia), anaphylaxis, angioneurotic edema, acute interstitial nephritis, and small increases in serum creatinine.