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# Famotidine Injection (Famotidine Injection)

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The adverse reactions listed below have been reported during domestic and international clinical trials in approximately 2500 patients. In those controlled clinical trials in which famotidine tablets were compared to placebo, the incidence of adverse experiences in the group which received famotidine tablets, 40 mg at bedtime, was similar to that in the placebo group.

The following adverse reactions have been reported to occur in more than 1% of patients on therapy with famotidine in controlled clinical trials, and may be causally related to the drug: headache (4.7%), dizziness (1.3%), constipation (1.2%) and diarrhea (1.7%).

The following other adverse reactions have been reported infrequently in clinical trials or since the drug was marketed. The relationship to therapy with famotidine has been unclear in many cases. Within each category the adverse reactions are listed in order of decreasing severity:

fever, asthenia, fatigue: **Body as a Whole**

arrhythmia, AV block, palpitation: **Cardiovascular**

cholestatic jaundice, liver enzyme abnormalities, vomiting, nausea, abdominal discomfort, anorexia, dry mouth: **Gastrointestinal**

rare cases of agranulocytosis, pancytopenia, leukopenia, thrombocytopenia: **Hematologic**

anaphylaxis, angioedema, orbital or facial edema, urticaria, rash, conjunctival injection: **Hypersensitivity**

musculoskeletal pain including muscle cramps, arthralgia: **Musculoskeletal**

grand mal seizure; psychic disturbances, which were reversible in cases for which follow-up was obtained, including hallucinations, : **Nervous System/Psychiatric**  
confusion, agitation, depression, anxiety, decreased libido; paresthesia; insomnia; somnolence

bronchospasm: **Respiratory**

toxic epidermal necrolysis (very rare), alopecia, acne, pruritus, dry skin, flushing: **Skin**

tinnitus, taste disorder: **Special Senses**

rare cases of impotence and rare cases of gynecomastia have been reported; however, in controlled clinical trials, the incidences were not greater than : **Other**  
those seen with placebo.

The adverse reactions reported for famotidine tablets may also occur with famotidine for oral suspension, famotidine orally disintegrating tablets, famotidine injection preservative free in plastic container or famotidine injection.