Editorial Comment

Drs. Howden and Tytgat provide our readers with a comprehensive safety profile of famotidine, a specific and competitive histamine$_2$ (H_2)-receptor antagonist, which has been prescribed for an estimated 18.8 million patients worldwide over the last 10 years. These statistics make this class of drugs, which is used to promote healing of duodenal and gastric ulcers and erosive esophagitis, among the most frequently prescribed in the world.

A decade of use is a valid indicator of the postmarketing safety of a drug or class of drugs. The authors have focused on clinical adverse events in investigational trials of famotidine versus other drugs in the same class and placebo and found that its tolerability profile "remained substantially unchanged." Less than 3% of patients discontinued treatment with famotidine because of adverse events and this was similar to, or better than, placebo and other H_2-receptor antagonists.

Most adverse clinical events were not serious (gastrointestinal complaints, headache, and skin rash); serious adverse drug–related events were reported in 1.30% of 6938 participants in clinical development studies, 6.49% of 5458 in local studies, 1.08% of 49,692 in event-monitoring surveillance studies, and 1.96% of 4996 in investigational trials.

Laboratory adverse events were not serious and consisted mainly of elevated aspartate aminotransferase or alanine aminotransferase levels; headache and dizziness were most common in the elderly. Data from postmarketing studies, representing 13,000 patient-years, showed similar rates, which were consistent with previous experiences, and included patients with cardiovascular, renal, and hepatic dysfunction.

Indeed, the evaluation of the worldwide postmarketing and over-the-counter experiences shows famotidine to be a safe, well-tolerated, specific, long-acting, competitive H_2-receptor antagonist.

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