13 Overall Safety Conclusions

The use of Ome-Mg for occasional, episodic heartburn is expected to be safe and well tolerated in the OTC population based on results of OTC and Rx therapeutic trials and post-marketing safety data.

The pharmacokinetic and pharmacodynamic profile indicate that Ome-Mg can be used safely in the OTC population with intermittent heartburn. There are no clinically significant hepatic metabolic drug-drug interactions, but consumers are advised to consult with a physician when taking medications whose absorption is pH dependent. No dose adjustment is necessary is necessary in hepatic or renal impairment and slow metabolizers.

Reports of overdosage with omeprazole are rare. Reported symptoms of overdosage are transient without serious clinical consequences. There is no evidence to suggest that omeprazole has abuse potential nor is there evidence that it potentiates the effects of substances of abuse.

Based on long-term Rx studies, continuous use of omeprazole up to 80 mg/day for 2 or more years does not lead to clinically significant abnormalities in gastrointestinal mucosa, such as gastric ECL cell carcinoids or gastric or colonic malignancies.

The risk of esophageal or gastric cancer in individuals with heartburn symptoms is very low. Therefore, the use of Ome-Mg by consumers with intermittent heartburn is unlikely to pose an increased health risk or mask other diseases.

Based on review of current literature there are inconsistent data with respect to the development of rebound of gastric acid secretion following discontinuation of omeprazole treatment. The studies showing evidence of acid rebound following withdrawal of omeprazole therapy have mainly included patients taking doses of 40 mg daily for at least 8 weeks of therapy. Rebound of acid secretion therefore should not be associated with use of omeprazole in an OTC setting.

A review of post-marketing and clinical trial adverse events shows that anaphylaxis and angioedema with omeprazole use are rare events and there is no indication of an increased risk for occurrence of these adverse events with use of omeprazole.

Based upon review of worldwide post-marketing and clinical trial information regarding changes in hepatic function during use of omeprazole, the incidence of hepatic dysfunction, based on liver enzyme test results, in patients receiving omeprazole therapy is low. In most cases of serious hepatic adverse events, including those leading to fatalities, other possible causative or contributing factors were identified.

The review of worldwide serious and US non-serious post-marketing adverse event data do not suggest that there is an increased risk of developing visual adverse events when taking omeprazole.

The safety profile of omeprazole is well characterized based on the results of clinical trials in both the OTC and Rx settings as well as from worldwide post-marketing reports generated from over 300 million patient treatments during a 10 year time span. It would be expected that any adverse reactions associated with product use in the Rx setting should be less likely in the OTC setting because Rx use is at doses that are higher and for more prolonged time periods than the use recommended in the dosing instructions for the OTC product. While Ome-Mg is intended for use by consumers with intermittent heartburn, individuals with chronic heartburn are advised to seek medical attention for their symptoms.