AstraZeneca medical news

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AstraZeneca response to FDA and Health Canada communication regarding omeprazole and Nexium® (esomeprazole)

The FDA and Health Canada today issued public notifications on numerical differences in cardiac event rates reported from two small, non-blinded, long-term, clinical studies in patients with gastro-esophageal reflux disease (GERD), comparing anti-reflux surgery with either omeprazole* or Nexium® treatment. The notifications were in response to a communication sent to all Health Authorities by AstraZeneca in May 2007.

AstraZeneca agrees with the FDA in their preliminary assessment that "these data do not suggest an increased risk of heart problems for patients treated with omeprazole or esomeprazole" and that the observed differences in reported cardiac event rates in the two studies is not a true effect. It is the view of AstraZeneca that the study results conclude that the products are not associated with an increased risk of cardiac events and do not change the overall benefit/risk profile of omeprazole and Nexium®. Therefore, patients should not change their medication in the light of the study data. Pending their detailed analysis of the two studies, the FDA and Health Canada confirm that prescribing practices for omeprazole and Nexium® should not change. AstraZeneca fully supports efforts by FDA and Health Canada to ensure transparency of emerging safety information as it relates to marketed products.

Since the initial notification, AstraZeneca has forwarded to all Health Authorities near complete data from these two trials, as well as reviewed

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additional randomised controlled trial data from over 50,000 patients which collectively show that omeprazole and Nexium® are not associated with an increased risk of cardiac events.

The review of the data from the two studies demonstrate:

- that there are no differences in the cardiac event reporting rates between the treatment arms in the ongoing Nexium® study (LOTUS).
- that whilst the older, non-blinded omeprazole study (SOPRAN) shows an apparent difference in cardiac event reporting rates emerging during the first prior to 12 months of dosing, a separate evaluation of other controlled clinical trials of 12-24 months duration, involving omeprazole and placebo in approximately 2,900 patients, shows a lower cardiac event reporting rate amongst omeprazole treated patients than for placebo treated patients.

This conclusion has been further validated by an analysis of post-marketing safety data using the FDA and World Health Organisation spontaneous adverse event report safety databases. Both databases suggest no indication of an increased cardiac risk with any of the marketed PPI's, including omeprazole or Nexium®.

AstraZeneca has made all omeprazole long-term clinical trial results, including data from the above mentioned SOPRAN trial, as well as completed Nexium® trial results available on www.astrazenecaclinicaltrials.com/article/521037.aspx. Data from the above mentioned Nexium® (LOTUS) trial, which is ongoing, will be available online once the trial has been completed.

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Commenting on the data from the two studies, one of the world's leading experts in gastroenterology, Professor John Dent, Director, Nerve-Gut Research Laboratory, Department of Gastroenterology & Hepatology, Royal Adelaide Hospital, Australia, says: "It is not appropriate to draw any conclusions on cardiovascular safety from the LOTUS and SOPRAN studies as they were only designed to test major GERD treatment outcomes. Much evidence already exists from data gathered appropriately from very large numbers of patients for the purposes of risk assessment of omeprazole and esomeprazole therapy. These data show no evidence of these therapies being associated with increased risk for cardiovascular events. They extinguish any concerns raised by the SOPRAN and LOTUS data in the light of the lack of validity of the SOPRAN and LOTUS data from the perspective of cardiovascular risk assessment."

Patients who have questions related to this communication should discuss their treatment with their prescribing physicians. AstraZeneca will continue to work with the FDA and Health Canada in their ongoing review of additional data. Other Health Authorities who have reviewed the data have not indicated a need to change prescribing information on these PPI's based on this information.

Losec® (launched in 1988) and Nexium® (launched in 2000) have been shown to be beneficial for patients with acid related diseases such as GERD and NSAID associated ulcers. Proton pump inhibitors (PPI's) are generally well tolerated and Losec® and Nexium® have been used in the management of patients with acid related diseases in over 1 billion patient treatments.

- ENDS -

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* Omeprazole is widely available as generic and OTC medication.

AstraZeneca trade names for omeprazole include Losec®, Prilosec®, Antra®, Mopral®

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