

PA32540 safe for patients at risk of aspirin-linked upper GI events

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(HealthDay)—For subjects at risk of aspirin-associated upper

gastrointestinal (UGI) events, long-term PA32540 (enteric-coated aspirin 325 mg and immediate-release omeprazole 40 mg) appears to be safe, according to a study published in the April issue of *Cardiovascular Therapeutics*.

Jay L. Goldstein, M.D., from the NorthShore University HealthSystem in Evanston, Ill., and colleagues conducted a 12-month, open-label, multicenter phase 3 trial to examine the long-term cardiovascular and gastrointestinal [safety](#) of PA32540. Subjects who were taking aspirin 325 mg daily for three or more months for secondary cardiovascular disease prevention and were at risk for UGI events were enrolled. Participants received PA32540 once daily for up to 12 months; assessments were conducted at baseline and at months one, six, and 12.

The researchers found that the safety population included 379 subjects, of whom 76 percent were on PA32540 for 348 or more days (12-month completers). In 13.5 percent of patients, adverse events (AEs) caused study withdrawal, most often gastroesophageal reflux disease (1.1 percent). Seventy-six percent of the safety population and 73 percent of 12-month completers had treatment-emergent AEs (11 and 8 percent, respectively, were treatment related). Dyspepsia was the most common treatment-related AE (2 percent).

"Long-term treatment with PA32540 once daily for up to 12 months in subjects at risk for aspirin-associated UGI events is not associated with any new or unexpected safety [events](#)," the authors write.

Several authors disclosed financial ties to pharmaceutical companies, including POZEN Inc., which funded the study.

More information: [Abstract](#)
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