Extended-Release Acetaminophen Eased Knee OA

BY BRUCE JANCIN Denver Bureau

AMSTERDAM — For pain associated with knee osteoarthritis, extended-release acetaminophen is a possible alternative to cyclooxygenase-2 inhibitors, Dr. Thomas J. Schnitzer reported at the annual European Congress of Rheumatology.

Current osteoarthritis (OA) guidelines recommend the original shorter-acting formulation of acetaminophen at 4 g/day as a first-line treatment for pain associated with the disease. The extended-release formulation, which is commercially available, offers the advantage of less frequent dosing, explained Dr. Schnitzer, professor of medicine at Northwestern University, Chicago.

He reported on a 4-week, 23-center, double-blind U.S. clinical trial of 403 adults with knee OA. Participants were randomized to extended-release acetaminophen at the recommended adult dosage of 1,300 mg t.i.d., rofecoxib at 12.5

mg/day, or rofecoxib at 25 mg/day.

The mean 143.5-mm drop on the 0- to 500-mm visual analog scale in the acetaminophen group was not significantly different from the results with rofecoxib at 12.5 mg/day, but it was inferior to the 175.9-mm drop with high-dose rofecoxib.

Rheumatology

Study withdrawal rates for lack of efficacy were 1.5% with extended-release acetaminophen and 3.6% and 1.6%, respectively, for low- and high-dose rofecoxib. Dropout due to adverse events occurred in 5.9% of the acetaminophen group, 6.5% with rofecoxib 12.5 mg, and 7.0% with 25 mg. Headache was reported by 6.6% of patients on extended-release acetaminophen, vs. 0.7% on the low dose and 5.4% on the high dose of rofecoxib, Dr. Schnitzer noted. Two patients had an acute MI during the 4-week study, both in the rofecoxib 12.5-mg arm. Investigators deemed the MIs unrelated to the study medication.

The study was sponsored by McNeil Consumer Healthcare.



Important safety and other information

- for PREVACID were diarrhea (3.8%), abdominal pain (2.1%), and nausea (1.3%).
- Symptomatic response to therapy does not preclude the presence of gastric
- Individual results may vary

See adjacent page for brief summary of prescribing information.

*Excludes PBMs, employers groups, and state Medicaid. †Based on Formulary Compass™ managed care database available through MediMedia Information Technologies, December 28, 2005. At least one PREVACID product is covered. ‡Based on WAC (Wholesale Acquisition Cost) pricing per oral tablet/ capsule published by First DataBank, Inc., April 2006. WAC is a published price list; actual cost to pharmacy or consumer may differ.

Formulations & Indications

PREVACID HAS FORMULATIONS THAT MAY ADDRESS A BROAD RANGE OF PATIENT NEEDS. 1,3-5

