

Extended-Release OTC Agent Relieves Knee OA

BY BRUCE JANCIN
Denver Bureau

AMSTERDAM — Extended-release acetaminophen is a possible alternative to cyclooxygenase-2 inhibitors for pain associated with knee osteoarthritis, 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 403 adults with knee OA who participated in a 4-week, 23-center, double-blind U.S. clinical trial. 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.

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, compared with 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

- Adverse events reported most frequently 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 malignancy. PREVACID formulations are contraindicated in patients with known hypersensitivity to any component of the formulation.
- PREVACID products should not be crushed or chewed.
- Individual results may vary.
- Cost comparisons do not imply any information regarding safety or efficacy.

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.

Phenylketonurics: PREVACID SoluTab contains phenylalanine 2.5 mg per 15 mg tablet and 5.1 mg per 30 mg tablet.

References

1. PREVACID Complete Prescribing Information.
2. Data on file, TAP Pharmaceutical Products Inc.
3. PREVACID I.V. Complete Prescribing Information.
4. PREVPAC Complete Prescribing Information.
5. PREVACID NapraPAC Complete Prescribing Information.

Formulary Compass is not a trademark of TAP Pharmaceutical Products Inc.

©2006 TAP Pharmaceutical Products Inc. 2006-030-07908 05/06



Formulations & Indications

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



Individual patients. Individual answers.