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SPECIAL SELECTION

Radiology in Family Practice 213
Steven M. Gold, MD; Sally R. Shott, MD; Charles M. Myer III, MD

LIVING IN MEDICINE

A Mandate for Physician Activism in the War Against Tobacco 215
Margaret M. Barnes, MD

ORIGINAL CONTRIBUTIONS

The Decision to Seek Care: Factors Associated With the Propensity to Seek Care in a Community-Based Cohort of Men 218
Rosebud O. Roberts, MD; Thomas Rhodes, MS; Cynthia J. Girman, DrPH; Harry A. Guess, MD, PhD; Joseph E. Oesterling, MD; Michael M. Lieber, MD; Steven J. Jacobsen, MD, PhD

Periodic Health Examinations and the Provision of Cancer Prevention Services 223
Carol Hill Sox, Engr; Allen J. Dietrich, MD; Tor D. Tosteson, ScD; Charlotte Woodruff Winchell; Christine E. Labarre

Treatment Typically Provided for Comorbid Anxiety Disorders 231
Lisa S. Meredith, PhD; Cathy Donald Sherbourne, PhD; Catherine A. Jackson, PhD; Patti Camp, MS; Kenneth B. Wells, MD, MPH

Differential Diagnosis of Palpitations: Preliminary Development of a Screening Instrument 241
Arthur J. Barsky, MD; David K. Ahern, PhD; Beth A. Delamater; Susan A. Clancy, MA; E. Duff Bailey, MD

Modifiable High-Risk Behaviors for Cardiovascular Disease Among Family Physicians in the United States: A National Survey 246
Kim E. LeBlanc, MD; Isabel C. Scarinci, MA, MPH; Leanne L. LeBlanc, MD; Glenn N. Jones, PhD

Values, Stress, and Coping Among Practicing Family Physicians 252
Douglas M. Post, PhD

Efficacy of Diclofenac in Lateral Epicondylitis of the Elbow Also Treated With Immobilization 257
Hubert Labelle, MD; Rémi Guibert, MD, MSc; for the University of Montreal Orthopaedic Research Group

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Contraindicated in patients with hypersensitivity to DAYPRO or in individuals with nasal polyps, angioedema, or bronchospastic reactivity to aspirin or other NSAIDs. Severe and occasionally fatal asthmatic and anaphylactic reactions to NSAIDs have been reported; there have been rare reports of anaphylaxis with DAYPRO. As with other NSAIDs, the most frequently reported adverse reactions were related to the GI tract. In patients treated chronically with NSAID therapy, serious GI toxicity, such as bleeding, ulceration, and perforation, can occur. Severe renal and hepatic reactions have been reported. There may be a risk of fatal hepatitis with oxaprozin, such as has been seen with other NSAIDs.

Please see brief summary of prescribing information on adjacent page.
hepatic, hemolytic, and dermatologic adverse effects. Laboratory test interferences: False-positive urine immunoassay screening tests for benzodiazepines have been reported in patients taking Daypro. This may lead to increased false-positive test results. False-positive test results may be expected for several days following discontinuation of Daypro. Drug interactions: Daypro is not a substrate, inducer, or inhibitor of CYP3A4 isoenzymes and is not expected to affect the metabolism of other drugs. In vitro studies have shown that the oral bioavailability of oxaprozin is not significantly influenced by concomitant administration with commonly prescribed prasugrel, clopidogrel, aspirin, statins, or calcium channel blockers.

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**INDICATIONS AND USAGE:** Daypro is indicated for the treatment of the signs and symptoms of OA and RA.

**CONTRAINDICATIONS:** Hypersensitivity to oxaprozin or any of its components or in individuals with complete or partial syndrome of nasal polyps, angioedema, and bronchospastic reactivity to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). Severe cardiac, hepatic, or renal disease or severe ulcerating reactions in patients receiving NSAIDs, and there have been rare reports of anaphylaxis in patients taking oxaprozin.

**WARNINGS:** RISK OF GASTROINTESTINAL ILLIGENCE, BLEEDING, AND PERFORATION WITH NONSTEROIDAL ANTI-INFLAMMATORY DRUG THERAPY: Serious gastrointestinal toxicity, such as bleeding, ulceration, and perforation, can occur at any time, with or without warning symptoms. The STEEL (Surgical Therapeutics Effectiveness Evaluation in Long-term Use) study involving over 10,000 patients demonstrated a steady increase in the risk of ulcers over time in patients treated with Daypro in just under 1% of patients. A patient with symptoms and/or signs suggesting ulcer dysfunction or in whom an abnormal liver test has occurred should be evaluated for evidence of development of mucosal ulceration and bleeding and management with or without discontinuation of the drug. Severe hepatic reactions including jaundice have been reported with Daypro, and there may be a risk of fatal hepatotoxicity with oxaprozin, such as has been seen with other drugs in this class.

**PRECAUTIONS:** General: Hepatic effects: As with other NSAIDs, borderline elevations of one or more liver tests may occur in up to 1% of patients. These abnormalities may not be reversible. Clinical endpoints, such as elevated liver enzymes, have been observed in patients with chronic hepatic disease, and the liver disease is not reversed by oxaprozin. ALT (alanine transaminase) test is probably the most sensitive indicator of liver dysfunction. Meaningful increases in the upper limits of normal for ALT, AST (aspartate transaminase), alkaline phosphatase, and serum bilirubin occurred in 1% of patients treated with Daypro in the STEEL study. Reactivated hepatitis or hepatitis-like reactions have been reported in patients taking Daypro.

**REPRODUCTION:** PREGNANCY: Category C. Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. It is not known whether oxaprozin can cause fetal harm when administered to a pregnant woman. DAYPRO should not be used in women who are or may become pregnant, except in the rare instance when the potential benefit justifies the potential risk to the fetus. GERIATRIC USE: Safety and efficacy of oxaprozin in the elderly have not been established. See Precautions: Geriatric use: Oxaprozin is known to have caused decreases in pup survival in rat studies. Accordingly, the use of oxaprozin during late pregnancy should be avoided. Nursing mothers: Studies of oxaprozin excruted into breast milk are not available. It is not known whether oxaprozin is excreted in human milk or if it could cause adverse effects when administered to a nursing mother. Daypro was found in the milk of lactating rats. Since the effects of oxaprozin on infants are not known, caution should be exercised if Daypro is administered to nursing women. Refuge: Safety and effectiveness of oxaprozin have not been established in patients with hepatic disease. Oxaprozin is not excreted in the urine so patients with renal impairment should be treated with caution. Long-term use in patients with renal impairment is not recommended.

**ADVERSE REACTIONS:** The most frequently reported adverse reactions were related to the gastrointestinal tract. In clinical trials the following adverse reactions occurred at an incidence greater than 1% and are probably related to treatment. Reactions occurring in 2% to 5% of patients treated with Daypro are listed in Table 1. Reactions occurring in less than 3% of patients are unremarked. Abdominal pain, diarrhea, constipation, nausea, vomiting, flatulence, anorexia, dry mouth, feeling of fullness, dyspepsia, and dysuria. In clinical trials, oxaprozin was significantly more effective than placebo in reducing pain and improving mobility. Drug Interactions: Measured on an NSAID basis, there is no evidence of drug interaction of Daypro with other drugs that are known to cause hepatic enzymes. Daypro has not been shown to be a substrate for the cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and Daypro is not expected to affect the metabolic activity of these enzymes. Drug Metabolism: Daypro is an inhibitor of cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and Daypro is not expected to affect the metabolic activity of these enzymes. Drug Metabolism: Daypro is an inhibitor of cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and Daypro is not expected to affect the metabolic activity of these enzymes.

**OVERDOSAGE:** No patient experienced either an accidental or intentional overdose of Daypro in the clinical trials of the drug. Symptoms following acute overdose with oxaprozin included anorexia, nausea, vomiting, and diarrhea, and are generally reversible with supportive care. Gastrintestinal bleeding and coma have been reported following an accidental ingestion of oxaprozin. **Forcible diuresis, alkalization of the urine, or hemodialysis would probably not be useful due to the high degree of protein binding of oxaprozin.** See package insert for complete prescribing information.
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Esther Entin, MD
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