New products and services briefing

Listings are prepared from information supplied by the companies cited or by their agents and are presented for informational value only. Publication in no way constitutes endorsement or warranty by The Journal of the American Osteopathic Association *or by the American Osteopathic Association. In contacting these companies, please mention* JAOA.

Sphygmomanometer

The wall-mount aneroid sphygmomanometer features a 90-degree swivel movement capability for accurate blood pressure readings from any angle. The unit has a 10-degree tilt variability to reduce overhead glare. Both the wall unit and mobile sphygmomanometer contain no mercury. For more information, contact Welch Allyn, Inc, Medical Division, 4341 State Street Rd, PO Box 220, Skaneateles Falls, NY 13153-0220; (315) 685-4560.

Magnification system

The Hi-Scope electronic medical magnification system features a portable, hand-held, video camera and a video screen that magnifies anatomy 50 to 1000 times. The camera can be used to examine the entire external or exposed internal area during invasive surgery. A narrow probe enables examination of the inner ear or upper nasal cavity respiratory chambers. Viewed areas can be stored on videotape, a floppy computer disk, or printed from a color video printer. For more information, contact Hirox/Win Systems of America, 299 Pleasant St, Haworth, NJ 07641; (800) 772-4658.

Oral antibiotic

Biaxin™ (clarithromycin) is now available as an oral antibiotic intended for treating repiratory tract and skin structure infections. The clarithromycin tablets are available in 250-mg and 500-mg doses, with a recommended dosage of two tablets daily. For more information, contact Abbott Laboratories, One Abbott Park Rd, Abbott Park, IL 60064-3500; (708) 937-5968.

Antithrombotic agent

Available in 250-mg tablets, Ticlid® (ticlopidine hydrochloride) is intended to reduce the risk of fatal and nonfatal thrombotic stroke in patients who have had stroke precursors or who have had an actual stroke. The recommended initial dosage is 250 mg two times daily, with food. This antithrombotic agent is contraindicated in persons with a hypersensitivity to ticlopidine hydrochloride; persons who have hematopoietic disorders, such as neutropenia and thrombocytopenia; persons with a hemostatic disorder or active pathologic bleeding; and individuals with severe liver impairment. For more information, contact Syntex Laboratories, 3401 Hill View Ave, PO Box 10850, Palo Alto, CA 94304; (415) 852-1321.

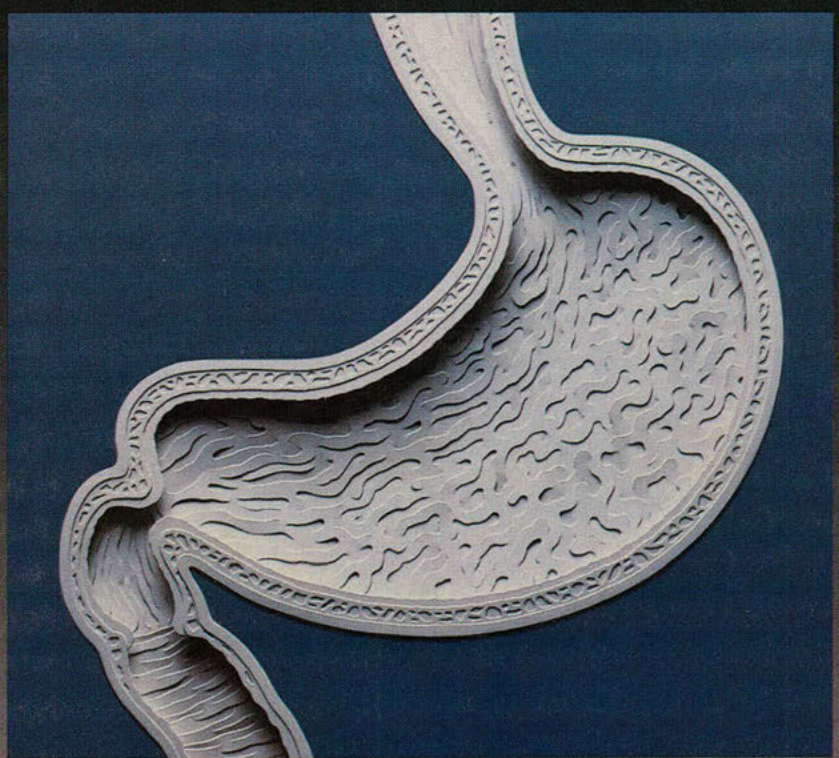
Estrogen transdermal patch

Estraderm® (estradiol transdermal system) continuously delivers 17-β-estradiol through a rate-limiting membrane. The patch provides nominal in vivo delivery of 0.05 mg or 0.1 mg of estradiol daily. Each patch contains 4 mg or 8 mg of estradiol and 0.3 or 0.6 mL of alcohol. It is intended for the treatment of vasomotor symptoms associated with menopause; female hypogonadism; primary ovarian failure; atrophic vaginitis and kraurosis vulvae; and as a preventive treatment for osteoporosis. For more information, contact CIBA Pharmaceutical Co, Division of CIBA-GEIGY Corp, 556 Morris Ave, Summit, NJ 07901; (201) 277-5000.

In arthritis therapy:

Because you're concerned about G.I. reactions...

NSAIDs may adversely affect the hematologic, hepatic, renal, and gastrointestinal systems, although G.I. reactions occur most frequently.



Start with

25·50·75-MG TABLETS

Voltaren®

diclofenac sodium

*An established record of G.I. tolerability.**

*Contraindicated in patients hypersensitive to aspirin, other NSAIDs, or Voltaren. As with other NSAIDs, the most frequent complaints relate to the G.I. tract. In patients treated chronically with NSAID therapy, serious G.I. toxicity such as bleeding, ulceration, and perforation can occur. Elevations of SGOT and/or SGPT, some significant, have been reported in association with Voltaren treatment; cases of severe hepatic reactions have rarely been reported.

Please see following page for brief summary of Prescribing Information.

Voltaren®
diclofenac sodium
Enteric-Coated Tablets
Brief Summary (See full Prescribing Information)

INDICATIONS AND USAGE
Voltaren is indicated for acute and chronic treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis.

CONTRAINDICATIONS
Patients with hypersensitivity to it, in whom Voltaren, aspirin, or other nonsteroidal anti-inflammatory drugs induce asthma, urticaria, or other allergic-type reactions.

WARNINGS
Gastrointestinal Effects
Risk of G.I. ulcerations, bleeding and perforation with nonsteroidal anti-inflammatory therapy: Serious G.I. toxicity can occur at any time, with or without warning symptoms, during chronic treatment. The occurrence is about 1% after 3-6 months, 2-4% after a year. Patients should be informed of signs and symptoms of serious G.I. toxicity and what to do if it occurs. No subset of patients not at risk has been identified. Prior history of serious G.I. events and other risk factors of peptic ulcer disease, e.g., alcoholism, smoking, etc., have been associated with increased risk. The elderly and debilitated tolerate ulceration and bleeding less well than other individuals and most spontaneous reports of fatal G.I. events are in this population. G.I. ulceration and bleeding can occur without warning symptoms and chronically treated patients should be followed. It is recommended that patients be maintained on the lowest dose of diclofenac sodium possible consistent with achieving a satisfactory therapeutic response.
Hepatic Effects
As with other nonsteroidal anti-inflammatory drugs, elevations of one or more liver tests may occur during Voltaren therapy. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continued therapy. Borderline elevations, (i.e., 1.2-3 times the upper limit of normal [ULN]), or greater elevations of transaminases occurred in about 15% of Voltaren-treated patients. The SGPT (ALT) test is probably the most sensitive indicator of liver injury. In clinical trials, meaningful elevations (i.e., more than 3 times the ULN) of SGOT (SGPT was not measured in all studies) occurred in about 2% of approximately 5700 patients at some time during Voltaren treatment. In a large, open, controlled trial, meaningful elevations of SGOT and/or SGPT occurred in about 4% of 3700 patients treated for 2-6 months, including marked elevations (i.e., more than 8 times the ULN) in about 1% of the 3700 patients. In that open-label study, a lower incidence of borderline (1.2-3 times the ULN), moderate (3-8 times the ULN), and marked (>8 times the ULN) elevations of SGOT or SGPT was observed in patients randomized to other NSAIDs. Transaminase elevations were seen more frequently in patients with osteoarthritis than in those with rheumatoid arthritis (see ADVERSE REACTIONS).

Transaminase elevations were reversible on cessation of therapy, and among 51 patients in all studies with marked elevations, signs and symptoms of liver disease occurred in only 3 cases, and only 1 patient developed jaundice. Most patients with borderline elevations did not have therapy interrupted; transaminase elevations in most of these cases disappeared or did not progress. There were no identifying features to distinguish those patients who developed marked elevations from those who did not.

In addition to the enzyme elevations seen in clinical trials, rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, have been reported.

Because severe hepatotoxicity may develop without a prodrome of distinguishing symptoms, physicians should measure transaminases periodically in patients receiving long-term therapy with Voltaren. The optimum times for making the first and subsequent transaminase measurements are not known. In the largest U.S. trial (open-label), which involved 3700 patients monitored first at 8 weeks and 1200 patients monitored again at 24 weeks, almost all meaningful elevations in transaminases were detected before patients became symptomatic. In 42 of the 51 patients in all trials who developed marked transaminase elevations, abnormal tests occurred during the first 2 months of therapy with Voltaren. Based on this experience the first transaminase measurement should be made no later than 8 weeks after the start of Voltaren treatment. As with other NSAIDs, if abnormal liver tests persist or worsen, if clinical signs and/or symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), Voltaren should be discontinued.

To minimize the possibility that hepatic injury will become severe between transaminase measurements, physicians should inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness and "flu-like" symptoms), and the appropriate action to take should these signs and symptoms appear.

PRECAUTIONS
Allergic Reactions: As with other nonsteroidal anti-inflammatory drugs, allergic reactions including anaphylaxis, have been reported.

Fluid Retention and Edema: Fluid retention and edema have been observed in some patients taking Voltaren.

Renal Effects: Cases of significant renal failure in patients receiving Voltaren have been reported from postmarketing experience, but were not observed in over 4,000 patients in clinical trials during which serum creatinines and BUNs were followed serially. Since Voltaren metabolites are eliminated primarily by the kidneys, patients with significantly impaired renal function should be more closely monitored than subjects with normal renal function.

Porphyria: The use of diclofenac in patients with hepatic porphyria should be avoided.

Drug Interactions
Aspirin: Concomitant administration of Voltaren and aspirin is not recommended.

Anticoagulants: NSAIDs affect platelet function as well, concurrent therapy with all NSAIDs, including Voltaren, and warfarin requires close monitoring of patients to be certain that no change in their anticoagulant dosage is required.

Digoxin, Methotrexate, Cyclosporine: Voltaren, like other NSAIDs, through effects on renal prostaglandins, may cause increased toxicity of digoxin, methotrexate, and cyclosporine.

Lithium: Voltaren decreases lithium renal clearance and increases lithium plasma levels. In patients taking Voltaren and lithium concomitantly, lithium toxicity may develop.

Oral Hypoglycemics: Physicians should consider the possibility that diclofenac may alter a diabetic patient's response to insulin or oral hypoglycemic agents.

Diuretics: Voltaren and other NSAIDs can inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels.

Other Drugs: In small groups of patients (7-10/interaction study), the concomitant administration of azathioprine, gold, chloroquine, D-penicillamine, prednisolone, doxycycline, or digitoxin did not significantly affect the peak levels and AUC values of Voltaren.

Drug/Laboratory Test Interactions
Effect on Blood Coagulation: Voltaren increases platelet aggregation time but does not affect bleeding time, plasma thrombin clotting time, plasma fibrinogen, or factors V and VII to XII.

Pregnancy Category B
There are no adequate and well-controlled studies in pregnant women. Voltaren should be used during pregnancy only if the benefits to the mother justify the potential risk to the fetus. Because of the known effects of prostaglandin-inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), use of Voltaren during late pregnancy should be avoided.

Labor and Delivery
The effects of Voltaren on labor and delivery in pregnant women are unknown. However, as with other nonsteroidal anti-inflammatory drugs, it is possible that Voltaren may inhibit uterine contraction.

Nursing Mothers
Voltaren has been found in the milk of nursing mothers. As with other drugs that are excreted in milk, Voltaren is not recommended for use in nursing women.

Pediatric Use
Dosage recommendations and indications for use in children have not been established.

ADVERSE REACTIONS
The incidence of common adverse reactions (greater than 1%) is based upon controlled clinical trials in 1543 patients treated up to 13 weeks. By far the most common adverse effects were gastrointestinal symptoms, most of them minor, occurring in about 20%, and leading to discontinuation in about 3%, of patients. Peptic ulcer or G.I. bleeding occurred in clinical trials in less than 1% of approximately 1800 patients during their first 3 months of diclofenac treatment and in less than 2% of approximately 800 patients followed for 1 year. Comparative rates were 0.2% for peptic ulcer or G.I. bleeding in approximately 2000 diclofenac-treated patients and 0.6% in approximately 600 aspirin-treated patients.

In double-blind trials there were fewer minor gastrointestinal complaints in 1227 patients treated with Voltaren than in 721 patients treated with aspirin, 22% vs 33% (compared to 13% on placebo).

The following adverse reactions were reported in patients treated with Voltaren:
Incidence Greater Than 1% (All derived from clinical trials.)

Body as a Whole: Abdominal pain or cramps*, headache*, fluid retention, abdominal distention.

Digestive: Diarrhea*, indigestion*, nausea*, constipation*, flatulence, liver test abnormalities, PUB, i.e., peptic ulcer, with or without bleeding and/or perforation, or bleeding without ulcer (see above and also WARNINGS).

Nervous System: Dizziness.

Skin and Appendages: Rash, pruritus.

Special senses: Tinnitus.

*Incidence, 3% to 9% (incidence of unmarked reactions is 1-3%)

Incidence Less Than 1%—Causal Relationship Probable (Adverse reactions reported only in the literature, not seen in clinical trials, are considered rare and are italicized.)

Body as a Whole: Malaise, swelling of lips and tongue, photosensitivity, *anaphylaxis*, anaphylactoid reactions.

Cardiovascular: Hypertension, congestive heart failure.

Digestive: Vomiting, jaundice, melena, aphthous stomatitis, dry mouth and mucous membranes, bloody diarrhea, hepatitis, appetite change, pancreatitis with or without concomitant hepatitis, *colitis*.

Hemic and Lymphatic: Hemoglobin decrease, leukopenia, thrombocytopenia, *hemolytic anemia, aplastic anemia, agranulocytosis,* purpura, *allergic purpura.*

Metabolic and Nutritional Disorders: Azotemia.

Nervous System: Insomnia, drowsiness, depression, diplopia, anxiety, irritability.

Respiratory: Epistaxis, asthma, laryngeal edema.

Skin and Appendages: Alopecia, urticaria, eczema, dermatitis, *bullous eruption, erythema multiforme major,* angioedema, *Stevens-Johnson syndrome.*

Special Senses: Blurred vision, taste disorder, reversible hearing loss, scotoma.

Urogenital: *Nephrotic syndrome,* proteinuria, *oliguria, interstitial nephritis, papillary necrosis, acute renal failure.*

Incidence Less Than 1%—Causal Relationship Unknown (Adverse reactions reported only in the literature, not seen in clinical trials, are considered rare and are italicized.)

Body as a Whole: Chest pain.

Cardiovascular: Palpitations, *flushing,* tachycardia, premature ventricular contractions, myocardial infarction.

Digestive: Esophageal lesions.

Hemic and Lymphatic: *Bruising.*

Metabolic and Nutritional Disorders: Hypoglycemia, *weight loss.*

Nervous System: Paresthesia, memory disturbance, nightmares, tremor, tic, *abnormal coordination,* convulsions, *disorientation, psychotic reaction.*

Respiratory: Dyspnea, hyperventilation, edema of pharynx.

Skin and Appendages: Excess perspiration, *exfoliative dermatitis.*

Special Senses: Vitreous floaters, night blindness, amblyopia.

Urogenital: Urinary frequency, nocturia, hematuria, impotence, vaginal bleeding.

C91-8 (Rev. 4/91)

References:
1. *Kolodny AL. Two double blind trials of diclofenac sodium with aspirin and with naproxen in the treatment of patients with rheumatoid arthritis.* J Rheumatol. *1988;15:1205-1211.*
2. *Data on file, CIBA-GEIGY Pharmaceuticals.*

Geigy
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