PHARMACIA

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Pfizer

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New York, NY 10017

IMPORTANT DRUG WARNING

November 13, 2002

Dear Healthcare Professional,

Pharmacia and Pfizer would like to inform you about recent changes to the product labeling for BEXTRA® (valdecoxib tablets). BEXTRA is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, and for the treatment of primary dysmenorrhea.

Since BEXTRA was approved by the FDA on November 16, 2001, in postmarketing experience, rare spontaneous reports of hypersensitivity reactions (i.e., anaphylactic reactions and angioedema) and skin reactions, including cases of Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis and erythema multiforme, have been received for patients treated with BEXTRA.

These cases, some of which were serious/life threatening, have occurred in patients with and without a history of allergic-type reactions to sulfonamides.

In order to communicate this important postmarketing information to healthcare professionals, the following information has been added to the package insert:

CONTRAINDICATIONS: BEXTRA should not be given to patients who have demonstrated allergic-type reactions to sulfonamides.

WARNINGS - Serious Skin Reactions: Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported through postmarketing surveillance in patients receiving BEXTRA (see ADVERSE REACTIONS-Postmarketing Experience). As these reactions can be life threatening, BEXTRA should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

WARNINGS - Anaphylactoid Reactions: In postmarketing experience, cases of hypersensitivity reactions (anaphylactic reactions and angioedema) have been reported in patients receiving BEXTRA (see ADVERSE REACTIONS-Postmarketing Experience). These cases have occurred in patients with and without a history of allergic-type reactions to sulfonamides (see CONTRAINDICATIONS).

ADVERSE REACTIONS - Postmarketing Experience: The following reactions have been identified during postmarketing use of BEXTRA. These reactions have been chosen for inclusion either due to their seriousness, reporting frequency, possible causal relationship to BEXTRA, or a combination of these factors. Because these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

General: Hypersensitivity reactions (including anaphylactic reactions and angioedema)
Skin and appendages: Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis

Pharmacia and Pfizer are committed to the safety and well being of all patients receiving BEXTRA (valdecoxib tablets). If you become aware of any case(s) of the events described above, in patients treated with BEXTRA, please report the event promptly. You may contact Pharmacia at 1-800-253-8600 extension 38244, or the FDA MedWatch program, by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857, or by the Internet at https://www.accessdata.fda.gov/scripts/medwatch/.

If you have any questions, please contact Pharmacia's Medical and Drug Information at 1-800-323-4204.

Please see the revised full prescribing information for BEXTRA enclosed with this letter.

Sincerely,

James B. Jones, MD, PharmD
Medical Director
Arthritis and Pain
Global Medical Affairs
Pharmacia Corporation

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Medical Director
COX-2 Worldwide Team
Pfizer Inc

