MedlinePlus Drug Information: Valdecoxib

On April 7, 2005, Pfizer, Inc., announced that valdecoxib (Bextra) will no longer be available in the United States. This action is based on advice from the Food and Drug Administration (FDA) about the potential for an increased risk of cardiovascular events (including heart attack and stroke) and serious skin reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) in patients taking valdecoxib compared to patients taking other nonsteroidal anti-inflammatory drugs (NSAIDs). Additionally, the FDA states that Bextra has not been shown to offer any unique advantages compared with the other available NSAIDs. If you are currently taking Bextra, you should call your doctor to discuss switching to another treatment. For more information visit the FDA website: http://www.fda.gov/cder/drug/infopage/COX2/default.htm.

Valdecoxib may cause severe skin reactions including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. These skin reactions may develop at any time during your treatment with valdecoxib, but are most likely to develop during the first 2 weeks of your treatment. Tell your doctor if you are allergic to valdecoxib, sulfa drugs, aspirin and other non-steroidal anti-inflammatory medications (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn), or any other medications. Also tell your doctor if you have ever had a severe rash. If you experience any of the following symptoms, stop taking valdecoxib and call your doctor immediately: rash; red skin; sores on the inside of your mouth, nose, eyes, throat, anus, or genital area; fever; chills; flu-like symptoms; hives; itching; swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs; difficulty breathing or swallowing; or hoarseness. Other medications similar to valdecoxib may also cause severe skin reactions, but the risk appears to be greater with valdecoxib. Talk to your doctor about the risk of taking valdecoxib.

Why is this medication prescribed? Return to top

Valdecoxib is used to relieve the pain, tenderness, inflammation (swelling), and stiffness caused by arthritis and to treat painful menstrual periods. Valdecoxib is in a class of nonsteroidal anti-inflammatory medications called COX-2 inhibitors. It works by stopping the body's production of a substance that causes pain and inflammation.

How should this medicine be used? Return to top

Valdecoxib comes as a tablet to take by mouth. It is usually taken with or without food once or twice a day. Follow the directions

on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take valdecoxib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking valdecoxib,

- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention any of the following: angiotensin-converting enzyme (ACE) inhibitors such as enalapril (Vasotec), fosinopril (Monopril), and lisinopril (Prinivil, Zestril); anticoagulants ('blood thinners') such as warfarin (Coumadin); antifungals such as fluconazole (Diflucan) and ketoconazole (Nizoral); aspirin; diuretics ('water pills'); lithium (Eskalith, Lithobid); and oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone (Deltasone). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have recently had coronary artery bypass graft surgery (CABG), a type of heart surgery) and if you have or have ever had ulcers, stomach bleeding, kidney or liver disease, heart failure, high blood pressure, swelling of legs and ankles, or asthma.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking valdecoxib, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking valdecoxib.
- ask your doctor about the safe use of alcoholic beverages while you are taking valdecoxib. Alcohol may increase the risk of side effects from valdecoxib.
- tell your doctor if you use tobacco products. Cigarette smoking may increase the risk of side effects from valdecoxib.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Valdecoxib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- stomach pain
- diarrhea
- heartburn
- back pain
- headache

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- chest pain
- black and tarry stools
- red blood in stools
- bloody vomit
- vomiting material that looks like coffee grounds
- unexplained weight gain
- upset stomach
- extreme tiredness
- lack of energy
- pain in the right upper part of the stomach
- yellowing of the skin or eyes
Valdecoxib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at http://www.fda.gov/MedWatch/report.htm] or by phone [1-800-332-1088].

**What storage conditions are needed for this medicine?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

**In case of emergency/overdose**

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

**What other information should I know?**

Keep all appointments with your doctor. Your doctor may order certain lab tests to check your body's response to valdecoxib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

**Brand names**

- Bextra®

Last Revised - 10/01/2005