

## Information for Patients Taking *Bextra*, *Celebrex*, or Naproxen

*Bextra* (valdecoxib), *Celebrex* (celecoxib), and naproxen (*Aleve*, *Naprosyn*) are used mainly for pain such as arthritis pain. Many patients also use them for menstrual pain. Many experts are now concerned that *Bextra*, *Celebrex*, and naproxen can lead to an increased chance of heart problems or stroke. *Bextra* and *Celebrex* are similar to *Vioxx* which was just taken off the market due to these types of problems. Naproxen is a regular painkiller like *Motrin* or *Advil*.

The chance of a problem in any one patient is very low. It is important to remember that many millions of people have used these medicines and many are still using them. Researchers continuously conduct studies to learn more about the drugs. Recently, researchers were studying to see if *Celebrex* was useful to prevent colon cancer. During the course of the study researchers noticed that there was an increase in heart problems in the people who were taking *Celebrex*. These studies usually run for years and involve many patients. In this case it requires statistical calculations to determine that there was an increase in heart problems in the patients taking *Celebrex*. Just recently, the FDA issued a patient advisory statement on naproxen (*Aleve*, *Naprosyn*) which can be bought over-the-counter. Preliminary information from an Alzheimer's disease study showed some evidence of increased risk of cardiovascular events in patients taking naproxen. Any individual patient who has taken *Celebrex*, *Bextra*, or naproxen should not become overly concerned.

Since the problem seems to be related to cardiovascular disease, it makes sense to try to avoid *Bextra* or *Celebrex* in patients who have heart problems. The FDA recently added that *Bextra* should not be used after coronary bypass surgery. Patients who have heart trouble and are taking *Bextra*, *Celebrex*, or naproxen should talk with their health care professional to see if some other therapy might be better for them.

*Bextra*, *Celebrex*, and *Vioxx* are called COX-2 inhibitor drugs. These drugs are actually in the same family of drugs that are called nonsteroidal anti-inflammatory drugs (NSAIDs). One of the problems with some nonsteroidal anti-inflammatory drugs (NSAIDs) is that they can sometimes lead to bleeding in the stomach. It was thought that the COX-2 drugs such as *Bextra*, *Celebrex*, and *Vioxx* would not lead to as much bleeding in the stomach as the other nonsteroidal anti-inflammatory drugs (NSAIDs). So patients who had ulcers or other chance of bleeding in the stomach or intestinal track often got a drug like *Bextra*, *Celebrex*, or *Vioxx* instead of the regular nonsteroidal anti-inflammatory drugs (NSAIDs). Pharmaceutical firms encouraged physicians to use these COX-2 drugs for many people. Many people might be better off on an NSAID (such as *Motrin*, *Advil*, or a store's brand product), or acetaminophen (such as *Tylenol* or a store's brand product). The FDA advises that patients should not exceed the recommended dose or duration printed on any over-the-counter medicine bottle unless a physician directs otherwise. Patients should discuss this with their pharmacist, nurse practitioner, physician assistant, and/or physician.

There is a separate concern related to *Bextra*. It can lead to severe rash, especially in the first two weeks when starting therapy. A patient taking *Bextra* should immediately report any severe rash, hives, or swelling to their physician or pharmacist. *Bextra* should be stopped right away when these appear. *Bextra* shouldn't be used in a patient who has a sulfa allergy. This includes patients who have had a real allergy to a sulfa drug. This does not include people who think they might be allergic to sulphates or other similar-sounding products or foods.

For more information go to:

<http://www.fda.gov/bbs/topics/news/2004/NEW01144.html>

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