

Safety of Entire Family of Painkillers Questioned

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WEDNESDAY, Nov. 24 (HealthDayNews) -- The withdrawal of Vioxx from the market in September and more recent concerns about its cousin Bextra have raised safety questions about this entire class of painkillers: Are there one or two bad apples, or is the bunch spoiled?

Consumers, physicians, and now regulatory agencies as well have been brought into the argument. Two key advisory committees of the U.S. Food and Drug Administration (news - web sites) will be looking into the safety of this class, called cox-2 inhibitors or coxibs, in mid-February.

Merck & Co., Inc., pulled Vioxx off the market when a trial showed that its users had nearly twice the risk of heart attack and stroke. Preliminary information shows that Bextra may have similar problems among patients with heart disease. Pfizer, Inc., which makes Bextra, disputed the information, but has said it will add a black box warning about a potentially fatal skin reaction.

Despite the controversy, not everyone is agreed on the future of drugs that were once hailed as a breakthrough for being able to relieve pain without the traditional gastrointestinal (GI) complications of nonsteroidal anti-inflammatory drugs (NSAIDs).

"We don't know that any of the cox-2 inhibitors are perfectly safe," said Dr. Eric Topol, chairman of cardiovascular medicine and chief academic officer of the Cleveland Clinic, who was one of the first to

speak out about possible problems. "Two out of three are already signed on as being problematic. One has been withdrawn [Vioxx], one is probably getting a black box [Bextra], and Celebrex may be a small hazard, but we just don't know."

Physicians who are in the business of treating arthritis sufferers, however, believe there may still be a place for these drugs.

"If patients are at a higher risk than normal for ulcers, this is a great choice," said Dr. Todd Schlifstein, assistant professor of rehabilitation medicine at New York University School of Medicine. "I feel comfortable prescribing those two [Celebrex and Bextra]. I have no hesitation. Obviously, if they have a history of cardiovascular disease, heart attacks, stroke or high blood pressure, I would use them cautiously."

"I think they have a place. They certainly work in a lot of people," said Dr. Stephen Lindsey, section head of rheumatology at the Ochsner Clinic Foundation in Baton Rouge, La. "A lot of people didn't respond to other drugs."

The main concern among these doctors was the high proportion of complications experienced by people on traditional NSAIDs.

According to Schlifstein, 16,500 people die every year from NSAID-related GI complications, and another 131,000 go to the emergency room. "We're talking billions of dollars and thousands of lives that these things save," he said. "That's the reason we put people on these things. If we put everyone back on ibuprofen, clear out the emergency room and get ready for the bleeds."

"Most people who were on Vioxx were on it for a reason. It has less GI toxicity. It decreased ulcer complications and death from ulcer disease," Lindsey added. "You should never use the normal nonsteroidals on elderly people who have a lot of co-morbidity."

By the same token, people with any kind of heart disease or risk factors for heart disease, such as high blood pressure, should probably never have been on Vioxx in the first place. Those complications had already been noted.

"I think if we just avoided people with severe heart disease, that would probably take care of most of the problems with Vioxx," Lindsey said. "The problems were with higher doses and people with heart disease."

When Vioxx was first pulled, Lindsey switched many of his patients to Celebrex, which "appears to have the best data and the least risk," he said. Most people taking these drugs for pain never approach the high doses used in the clinical trials, he pointed out.

This group of drugs may be particularly well suited for acute pain, which does not require long-term therapy, Lindsey added. "For five to 10 days, it's probably very safe," he said.

Topol, however, recommended that people with arthritis and health problems should take naproxen (Naprosyn, Aleve).

More information

For more on arthritis drugs, visit the Arthritis Foundation.