Alert for Healthcare Professionals

Valdecoxib (marketed as Bextra)

FDA Alert [04/07/05]:

FDA has requested that Pfizer voluntarily withdraw Bextra from the United States market. Pfizer has agreed to suspend sales and marketing of Bextra in the United States, pending further discussion with the Agency. At this time, the Agency has concluded that the overall risk versus benefit profile of Bextra is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that Bextra has not been shown to offer any unique advantages over the other available NSAIDs.

This information reflects FDA's current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

Recommendations

- FDA recommends that patients being treated with Bextra be switched to an alternative therapy.

Data Summary

- Bextra has been demonstrated to be associated with an increased risk of serious adverse CV events in two short-term trials in patients immediately post-operative from coronary artery bypass graft (CABG) surgery. Data are not available from long-term controlled clinical trials to evaluate the cardiovascular safety of Bextra following chronic use. FDA has concluded that it is reasonable to extrapolate the adverse CV risk information for Bextra from the short-term CABG trials to chronic use given the fact that other COX-2 selective NSAIDs have been shown in long-term controlled clinical trials to be associated with an increased risk of serious adverse CV events (e.g., death, MI, stroke), and the well described risk of serious, and often life-threatening gastrointestinal bleeding.
- Bextra is a sulfonamide and already carries a boxed warning in the package insert for serious and potentially life-threatening skin reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme). The reporting rate to FDA's spontaneous reporting system for these serious skin reactions is significantly greater for Bextra than other COX-2 selective agents. The risk of these serious skin reactions in individual patients is unpredictable, occurring in patients with and without a history of sulfa allergy, and after both short- and long term use.
- To date, there have been no studies that demonstrate an advantage of Bextra over other NSAIDs that might offset the concern about these serious skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.

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- Extensive data related to the cardiovascular safety of Bextra and other COX-2 selective and non-selective NSAIDs were presented at the Joint Meeting on February 16, 17, and 18, 2005, of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This information is available on the following website: http://www.fda.gov/ohrms/dockets/ac/cder05.html#ArthritisDrugs