



Alert for Healthcare Professionals

Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*

FDA Alert [04/07/05]:

Based on a review of available data from long-term placebo- and active-controlled clinical trials of non-steroidal anti-inflammatory drugs (NSAIDs), FDA has concluded that an increased risk of serious adverse cardiovascular (CV) events may be a class effect for NSAIDs (excluding aspirin). FDA has requested that the package insert for all NSAIDs be revised to include a boxed warning to highlight the potential increased risk of CV events and the well described risk of serious, and potentially life-threatening, GI bleeding. FDA has also requested that the package insert for all NSAIDs include a contraindication for use in patients immediately post-operative from coronary artery bypass graft (CABG) surgery.

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

- Physicians are encouraged to carefully weigh the potential benefits and risks of NSAIDs and other treatment options for the condition to be treated before a decision is made to use an NSAID. If chronic use of an NSAID is selected for an individual patient, the lowest effective dose for the shortest duration consistent with individual patient treatment goals should be used.
- NSAIDs should not be used in patients who are immediately post-operative from CABG surgery.

Data Summary

- Extensive data on the cardiovascular safety of 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>

*A list of prescription NSAIDs is available on the Internet at <http://www.fda.gov/cder/infopage/cox2/default.htm>.



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www.fda.gov/medwatch/report/hcp.htm
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