

## FDA says NSAIDS increase risk of heart attack

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The U.S. Food and Drug Administration (FDA) is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke.<sup>1</sup> Nonsteroidal anti-inflammatory drugs (NSAIDs) are drugs with analgesic, anti-inflammatory, and antipyretic activity.<sup>3</sup>

The results of both interventional and observational studies point towards the increased CV risk being a class effect of NSAIDs.<sup>3</sup> Based on FDA review and the advisory committees' recommendations, the prescription NSAID labels will be revised to reflect the following information<sup>1</sup>:

- The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.<sup>1</sup>
- The risk appears greater at higher doses.<sup>1</sup>
- NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease.<sup>1</sup>
- In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.<sup>1</sup>
- Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.<sup>1</sup>
- There is an increased risk of heart failure with NSAID use<sup>1</sup>

Stop taking NSAIDs and seek medical help if you experience symptoms that might signal heart problems or stroke, such as chest pain, trouble breathing, sudden weakness in one part or side of the body, or sudden slurred speech.<sup>2</sup>

NSAIDs are effective treatments for pain, inflammation and fever. Consumers can still take them but should be aware of this increased risk of heart attack or stroke, especially at higher doses.<sup>2</sup>

In addition, it is important to point out in a retrospective cohort study it was concluded that topical NSAID users experienced a reduced risk of cardiovascular events compared with oral NSAID users.<sup>4</sup> The crude cardiovascular event rate was 1.87 per 100 person-years for topical NSAIDs and 2.14 per 100 person-years for oral NSAIDs.<sup>4</sup> Results of propensity score weighted Cox regression found the topical NSAID group had 36% lower risk for cardiovascular events compared with the oral NSAID group (hazard ratio, 0.64; 95% confidence interval, 0.43–0.95).<sup>4</sup>

Topical NSAIDs may provide symptom relief without associated systemic adverse events because of favorable pharmacokinetic and pharmacodynamic properties, topical nonselective NSAIDs may be a safer alternative for relieving muscle-skeletal pain in patients with cardiovascular diseases.<sup>4</sup>

### References:

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