Taking Ibuprofen and Low-Dose Aspirin Simultaneously Can Decrease Cardioprotective Effects of Aspirin

Patients who take low-dose aspirin as a means to prevent heart attack or stroke may be taking it in conjunction with other medications, including pain relievers like ibuprofen.

New data suggests that when low-dose aspirin and ibuprofen are taken together, or within a specific period of time of each other, the beneficial effects of aspirin may be lost. This is thought to involve cyclooxygenase (COX), such that, when present, ibuprofen interferes with the binding of aspirin, thus decreasing the cardioprotective effects.

If your patient is taking:

- Low-dose (75-100mg), immediate release aspirin and ibuprofen 400mg, he/she may need to separate these medications. There are two options to preserve the benefit of aspirin:
  - Take ibuprofen 30 minutes after aspirin
  - Take ibuprofen 8 hours before aspirin

There is little evidence regarding the effects of ibuprofen on low-dose, enteric-coated aspirin, so at this time recommendations cannot be made.

Ketoprofen, diclofenac (Voltarin®), indomethacin (Indocin®), piroxicam, or prescription-dose (250-1000mg) naproxen may have a similar interaction with aspirin. If your patient is taking any of these medications, consider the recommendations mentioned above.

Please note that an occasional dose of ibuprofen is unlikely to interfere with the beneficial effects of aspirin. However, if your patient needs a pain reliever on a routine basis and would like to take all medications at the same time, acetaminophen does not appear to interfere with the cardioprotective effects of aspirin.

The recommendations outlined above are based on the limited research available. Further research is needed to determine, more thoroughly, the effects of ibuprofen and other painkillers on the beneficial effect of low-dose aspirin.


Did you know?

Overdoses of prescription opioid painkillers like oxycodone or fentanyl (often illegally obtained) have killed more Americans than cocaine or heroin, thus making prescription opioid painkillers the most common drugs that cause fatal overdoses in the United States.

Using government databases, Atlanta researchers for the U.S. Centers for Disease Control and Prevention analyzed information on death certificates. Researchers found an increase in both abuse and number of doctor prescriptions of opioid drugs.

Research concluded that “between 1979 and 1990, the mortality rate for unintentional drug poisoning increased nearly 60 percent, an increase of 5.3 percent per year.” Between 1990 and 2002, the rate increased 200 percent, an average of 18.1 percent per year.

(Reference: Finger Lakes Times Health Magazine, Illegal drugs and mortality, September 2006.)
**Ortho Evra® Update**

As previously reported in the March edition of *Rx Facts*, Ortho Evra, the contraceptive patch, exposes its users to approximately 60 percent more total estrogen than typical birth control pills.

On September 20, 2006, the FDA announced an update to the product's label, which included the findings of two epidemiology studies. **Results from these separate, ongoing studies provide contradicting results. One suggests there is no difference in the risk of blood clots between patch and typical pill users, while the other suggests a two-fold increase in risk for women using the patch.**

The FDA has stated that there is still no conclusive evidence of this link. However, the FDA remains concerned and recommends that women using the patch who are worried about clots (or who are at risk for clots) speak to their physicians.

*The studies are ongoing and new findings will continue to be provided to the FDA.*

It is important to note that, although rare, there is a risk of clots with all hormonal contraceptives. If you or your patients are interested in additional information about Ortho Evra, visit [www.fda.gov/cder/drug/infopage/orthoevra/](http://www.fda.gov/cder/drug/infopage/orthoevra/).

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**What's Happening with Generic Plavix®?**

One day generic Plavix is available — the next day the courts rule that it can no longer be distributed. What happened?

In January 2006, the FDA approved Apotex's generic clopidogrel, indicating it is bioequivalent to Bristol-Myers Squibb's (BMS) brand-name blockbuster Plavix, the world's second highest selling drug. When the FDA approves a generic medication, the approval is based on the manufacturer of the generic drug proving bioequivalence. The FDA is not concerned with patent protection. Therefore, once Apotex had FDA approval for clopidogrel, they released it to the market before the courts had ruled on whether or not the patent was valid.

This is called an "at risk" launch because if the generic drug manufacturer loses the court case, indicating the patent is valid, they will have to pay the brand-name manufacturer up to triple the damages. (Damages are determined by the profit the brand-name company loses during the time in which the generic drug is available.)

Typically, when a generic company attempts to launch a product “at risk,” the brand-name company will file a preliminary injunction to prevent the generic manufacturer from shipping any of the medication until the case is decided. However, in the case of Plavix, BMS and Apotex had a previous agreement that prohibited BMS from filing a preliminary injunction for at least five days. As a result, Apotex had a five-day window to ship clopidogrel (generic Plavix).

BMS's request for a preliminary injunction was granted, and the judge ordered Apotex to stop shipments of clopidogrel to distributors. However, the judge did not order a recall of any of the product already shipped.

Apotex was able to get over $500 million dollars worth of clopidogrel into the hands of distributors and pharmacies prior to the injunction. **Clopidogrel (generic Plavix) is expected to be available through the end of 2007, or longer, depending on how long the current supplies last.**