Propoxyphene: Withdrawal - Risk of Cardiac Toxicity(2)

U.S. Food & Drug Administration

AUDIENCE: Pain management, Pharmacy

ISSUE: FDA notified healthcare professionals that Xanodyne Pharmaceuticals has agreed to withdraw propoxyphene, an opioid pain reliever used to treat mild to moderate pain, from the U.S. market at the request of the FDA, due to new data showing that the drug can cause serious toxicity to the heart, even when used at therapeutic doses. FDA concluded that the safety risks of propoxyphene outweigh its benefits for pain relief at recommended doses. FDA requested that the generic manufacturers of propoxyphene-containing products remove their products as well.

BACKGROUND: FDA's recommendation is based on all available data including data from a new study that evaluated the effects that increasing doses of propoxyphene have on the heart (see Data Summary in Drug Safety Communication). The results of the new study showed that when propoxyphene was taken at therapeutic doses, there were significant changes to the electrical activity of the heart: prolonged PR interval, widened QRS complex and prolonged QT interval. These changes can increase the risk for serious abnormal heart rhythms.

RECOMMENDATION: FDA recommends that healthcare professionals stop prescribing and dispensing propoxyphene-containing products to patients, contact patients currently taking propoxyphene-containing products and ask them to discontinue the drug, inform patients of the risks associated with propoxyphene, and discuss alternative pain management strategies. Patients were advised to dispose of unused propoxyphene in household trash by following the recommendations outlined in the Federal Drug Disposal Guidelines. [1]

[11/19/2010 - Drug Safety Communication [2] - FDA]
[11/19/2010 - News Release [3] (with video) - FDA]

Supporting Documents:

[11/19/2010 - Updated Epidemiological Review of Propoxyphene Safety [4] - FDA]
[10/21/2010 - Multiple Ascending Dose (MAD) Study Review [5] - FDA]

SOURCE [6]

Source URL (retrieved on *03/08/2014 - 12:03pm*):
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toxicity2?qt-most_popular=0

Links:
[1] http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm226353.htm
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