FDA Orders Stronger Warning Placed on Labels of Drugs Containing Propoxyphene

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The Food and Drug Administration (FDA) has recently ordered manufacturers to place stronger warning labels on the prescription pain killer propoxyphene, commonly known as Darvon or Darvocet. Action has been taken due evidence of fatal overdoses, both accidental and intentional, involving propoxyphene. In Europe, recent data indicates that this medication could possibly be more lethal in overdose than other pain medications [5]. Propoxyphene has been on the market since 1957, and is an opiate commonly prescribed to relieve mild to moderate pain [4]. The most frequent side effects of propoxyphene include lightheadedness, dizziness, sedation, nausea, and vomiting [3].

Despite lobbying intended to eliminate propoxyphene from the market, the FDA has concluded at this time that the benefits of propoxyphene for pain relief at recommended doses outweigh the safety risks. Thus, the FDA is not suggesting the removal of propoxyphene products from the U.S. market [5]. Instead, the FDA will require manufacturers of propoxyphene to strengthen their labels by placing a boxed warning on each package, emphasizing the possible risks. Manufacturers are also required to provide consumers with a medication guide, highlighting the importance of using the drug as directed [2]. Furthermore, the FDA has required manufacturers to study higher than expected fatality rates in propoxyphene overdoses, versus those caused by other painkillers, as well as possible toxic effects on the heart when consumers exceed recommended doses [3].

More specifically, the following studies are in the planning process:

The FDA is working with CMS to study the safety and prescribing patterns of propoxyphene among the elderly. Notably, the FDA will look at the rates of fatalities and hip fractures among elderly patients taking propoxyphene, and compare these rates to those in elderly persons taking other analgesics.

The FDA plans to discuss a study examining the safety of propoxyphene with the Veterans Administration, using the VA's databases.

The FDA is planning to examine the safety of propoxyphene with one or more of its epidemiology contractors (Vanderbilt University, Kaiser – California, the HMO Research Network at Harvard Pilgrim Health, and Ingenix).

The FDA will also examine the possibility of reviewing Medical Examiner data in the Substance Abuse and Mental Health Administration's (SAMSHA) Drug Abuse Warning Network (DAWN) [5].

Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research (CDER) highlights the necessity of awareness about the danger of propoxyphene:

> "Physicians need to be aware of the risk of overdose when prescribing these drugs. They should carefully review patient histories and make appropriate treatment decisions based on the warnings and directions stated within the drug's label. Prescribers and patients should be aware of propoxyphene's potential risks when used at doses higher than those recommended. Therefore, the FDA is requiring manufacturers to provide more information to help physicians and patients decide whether propoxyphene is the appropriate pain therapy." [4]

Lastly, the FDA noted that it also plans to continue to evaluate the safety of propoxyphene and will take additional and immediate regulatory action if necessary [4].

Sources

[1] http://www.rxlist.com/darvon-drug.htm

[2] http://www.consumeraffairs.com/news04/2009/07/fda_darvon.html

[3] http://abcnews.go.com/Health/PainManagement/Story?id=8027102&page=1

[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm

[5] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm170268.htm