

Propoxyphene Withdrawal Due to Risk of Cardiac Toxicity A Significant Change for Workers' Compensation

After more than five decades of use in many millions of workers' compensation claims, the opioid analgesic propoxyphene is being withdrawn from the United States market. This is the result of a request from the Food and Drug Administration (FDA).

The FDA announced on November 19th that Xanodyne Pharmaceuticals has agreed to withdraw propoxyphene from the U.S. market. This withdrawal request was made due to new data showing that the drug can cause serious toxicity to the heart. This toxicity is seen even when used at therapeutic doses. Propoxyphene is dispensed in the United States as generic propoxyphene prescriptions and under the brand name drugs Darvon, Darvocet and others. The FDA has now also requested that the generic manufacturers of propoxyphene-containing products remove their products as soon as possible.

Possible Side Effects of Propoxyphene

New study results indicate that propoxyphene can cause significant changes to the electrical activity of the heart:

- Prolonged PR interval
- Widened QRS complex
- Prolonged QT interval

These changes can increase the risk for serious abnormal heart rhythms.

Immediate Action Recommended

The 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. The FDA further recommends that claimants be informed of the risks associated with propoxyphene and discuss alternative pain management strategies. Workers' compensation claimants are advised by the FDA to dispose of unused propoxyphene in household trash by following the recommendations outlined in the Federal Drug Disposal guidelines found at www.fda.gov.

Cypress Care's Responsibility to Our Clients

Senior Vice President of Pharmacy Services, Jim Andrews comments on the FDA's recommendation to withdraw propoxyphene from the market. "Cypress Care believes that our clinical team has a duty to inform our clients of any issues with medications that are used within the workers' compensation marketplace. As such, we want our clients to make our customers aware of the FDA's recent request to remove propoxyphene products from the market. FDA guidelines are typically enforced by the actual prescribing healthcare professionals and their patients. The FDA's ruling to withdraw these medications will result in physicians prescribing alternative drugs for pain management. Our clients will not need to intervene or take any additional action."

Until the drug is completely removed from the market, Cypress Care will continue to process claims that include propoxyphene or propoxyphene-containing medications unless instructed otherwise by our clients. To discuss any requested changes to your pharmacy program protocol or for more information, clients can contact their Cypress Care account executive.

Source: FDA MedWatch safety alert. Accessed 11/19/10.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm234389.htm>