



FDA Drug Safety Communication

FDA Drug Safety Communication: FDA recommends against continue use of propoxyphene

The FDA also called on drugmakers to stop marketing drugs containing the active ingredient in Darvon, called propoxyphene.

Propoxyphene is an opioid pain reliever used to treat mild to moderate pain. It is sold under various names as a single-ingredient product (e.g., Darvon) and as part of a combination product with acetaminophen (e.g., Darvocet).

The U.S. Food and Drug Administration (FDA) is recommending against continued prescribing and use of the pain reliever propoxyphene because new data show that the drug can cause serious toxicity to the heart, even when used at therapeutic doses. FDA has requested that companies voluntarily withdraw propoxyphene from the United States market.

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 below). 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, which can be seen on an electrocardiogram (ECG), can increase the risk for serious abnormal heart rhythms. FDA has concluded that the safety risks of propoxyphene outweigh its benefits for pain relief at recommended doses.

<http://www.fda.gov/Drugs/DrugSafety/ucm234338.htm#safety>

[Safety Announcement](#)

[Additional Information for Patients](#)

[Additional Information for Healthcare Professionals](#)

[Data Summary](#)

[References](#)

If you would like to pursue removing these drugs from your current pharmacy benefits, please contact your account manager for assistance.