

# Propoxyphene Products

(Darvocet®/Darvon®)

## Voluntary Recall

### IMPORTANT NOTICE

On November 19, 2010, the U.S. Food and Drug Administration (FDA) provided public notice recommending that propoxyphene-containing products no longer be prescribed or used due to new clinical data confirming use of these products, even in therapeutic doses, may place patients at increased risk for serious heart conditions. The brand name medications for propoxyphene are Darvocet and Darvon.

### BACKGROUND

In mid-2009, the FDA required manufactures of propoxyphene products strengthen labels to emphasize the risk for fatal overdose. In addition, the FDA required clinical trials be conducted to determine the effect on the heart if a patient used more than the recommended dose. Results of this clinical data indicates the use of propoxyphene may lead to significant heart conditions and places patients at risk for cardiac death. Patients with reduced kidney function, including elderly patients and those with advanced kidney disease, may be at an even greater risk. In response to these clinical findings, the FDA petitioned Xanodyne Pharmaceuticals, Inc. to voluntarily remove Darvon and Darvocet from the market. The FDA indicates it has also asked generic manufacturers of propoxyphene products to follow suit.

### PRODUCTS AFFECTED

The following is a list of all identified names of the propoxyphene products affected by this recall. All strengths are affected:

Products Affected	
Darvon	Propoxyphene
Darvocet-N®	Propoxyphene-acetaminophen
Darvon-N	Darvocet A500®
Balacet®	Propoxyphene powder for compounding



## NEXT STEPS

### PMSI Next Steps

As a result of the FDA’s withdrawal notification, and to ensure continued patient safety, PMSI has initiated a clinical response procedure. We are immediately taking the following actions:

- Propoxyphene has been removed from our formularies to ensure no further prescriptions are processed
- PMSI has quarantined all propoxyphene mail order pharmacy orders and initiated an outreach to patients, offering to contact their prescribers
- A physician alert letter is being sent to affected prescribers to inform them of the FDA’s actions and instruct them to utilize alternative agents

### Patient Next Steps

In order to ensure safety and well-being, the FDA recommends **patients** using propoxyphene products:

- Talk to their prescriber about discontinuing propoxyphene and switching to alternative pain medicines
- Talk to their prescriber if they have any concerns about propoxyphene
- Contact a healthcare professional right away if they experience an abnormal heart rate or rhythm or other symptoms including dizziness, lightheadedness, fainting or heart palpitations
- Report any side effects due to propoxyphene to the FDA’s MedWatch program at: <http://www.fda.gov/Safety/MedWatch/default.htm>

### Prescriber Next Steps

The FDA indicates that **prescribers** of propoxyphene products:

- Stop prescribing and dispensing propoxyphene-containing products to patients
- Contact patients taking propoxyphene-containing products and ask them to discontinue the drug
- Inform patients of risks associated with propoxyphene
- Discuss alternative pain management strategies other than propoxyphene with their patients
- Be aware of the possible risk of cardiac conduction abnormalities (prolonged QT, PR, and QRS intervals) in patients taking propoxyphene and assess patients if they present with any signs or symptoms of arrhythmia
- Report propoxyphene side effects to FDA’s MedWatch program at: <http://www.fda.gov/Safety/MedWatch/default.htm>

### ECONOMIC IMPACT

The economic impact of the withdrawal of these products will be determined by the agents that are used in its place. The chart below includes the propoxyphene product being recalled and their relative prices, as well as some of the alternative agents available.

Propoxyphene Product Being Recalled	Common Brand Name	Average Cost per Day Supply (generic formulation)
Propoxyphene HCl Cap 65 MG	Darvon	\$1.25
Propoxyphene Napsylate Tab 100 MG	Darvon-N	\$8.66
Propoxyphene HCl w/ APAP Tab 65-650 MG		\$1.28
Propoxyphene-N w/ APAP Tab 50-325 MG	Darvocet-N 50	\$2.60
Propoxyphene-N w/ APAP Tab 100-325 MG	Balacet 325	\$8.94
Propoxyphene-N w/ APAP Tab 100-500 MG	Darvocet A500	\$5.96
Propoxyphene-N w/ APAP Tab 100-650 MG	Darvocet-N 100	\$1.70



Alternative Products	Common Brand Name(s)	Average Cost per Day Supply (generic formulation)
Tramadol	Ultram	\$4.09
Tramadol-acetaminophen	Ultracet	\$3.65
Hydrocodone-acetaminophen	Vicodin, Lortab	\$1.42
Codeine-acetaminophen	Tylenol® #3	\$1.10
Acetaminophen	Tylenol	\$0.38
Ibuprofen	Advil®	\$0.56
Naproxen	Aleve	\$1.95

## CONCLUSION

This PMSI Drug Advisory is made available by our clinical pharmacist team to provide you with pertinent drug information and the potential impact upon your injured workers' care and your costs. As your pharmacy partner, PMSI understands the importance of staying on top of breaking news in the pain management arena and keeping you informed. We will continue to monitor and regularly communicate to you our proactive response to FDA recommendations to protect you and your clients' interests.

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## REFERENCES

FDA Press Release, "FDA Drug Safety Communication: FDA recommends against the continued use of propoxyphene" <http://www.fda.gov/Drugs/DrugSafety/ucm234338.htm>. Released November 19, 2010.

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