Poof! Darvon and Darvocet pulled from the market

If you have been taking propoxyphene (Darvon) or Darvocet (propoxyphene plus acetaminophen) for acute or chronic pain, you’re in for a big surprise when your next refill comes due. That’s because the FDA has asked Xanodyne Pharmaceuticals, maker of Darvon and Darvocet, to pull the drugs off the market and stop making them for sale in this country. The same thing goes for all generic forms of the drugs as well.

Propoxyphene (Darvon) is a narcotic that has helped millions of people in pain since it was first approved by the FDA in 1957. When acetaminophen was added to propoxyphene in the 1970s, it enhanced the pain-relieving properties of propoxyphene, and Darvocet was born. But recent clinical studies have shown that the drugs’ effectiveness in reducing pain is no longer enough to outweigh potentially serious heart rhythm disturbances caused by the drugs, according to the FDA. The FDA has recommended the following:

- Healthcare professionals stop prescribing and dispensing propoxyphene-containing products to patients.
- Contact patients currently taking propoxyphene-containing products and ask them to stop taking the drug.
- Inform patients of the risks associated with propoxyphene.
- Discuss alternative pain management strategies.
- Patients should dispose of unused propoxyphene in household trash after mixing the pills with some unpalatable substance like coffee grounds and sealing them in a zip lock container.
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As expected, lawyers who specialize in this sort of thing have sprinkled ads all over the Internet, advising patients who might have been injured by taking Darvon or Darvocet to call for a free consultation. “We’re ready to help whenever you need us,” said one ad.

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Changing subjects, the ACE inhibitor family of drugs is commonly used to treat high blood pressure. These drugs include the following by generic name with their brand name in parentheses:

- Benazepril (Lotensin)
- Captopril (Capoten)
- Enalapril (Vasotec)
- Fosinopril (Monopril)
- Lisinopril (Zestril and Prinivil)
- Moexipril (Univasc)
- Perindopril (Aceon)
- Quinapril (Accupril)
- Ramipril (Altace)
- Trandolapril (Mavik)

The labels for these drugs have long included a Black Box Warning that women who become pregnant should be taken off ACE inhibitor drugs as soon as possible to avoid exposing the fetus in the second and third trimesters, when they are known to cause fetal birth defects, especially involving the kidneys.

Now, a more recent study has raised doubt about the safety of these drugs even when taken during the first trimester of pregnancy. The uncontrolled study, published in 2006, showed that babies whose mothers had taken an ACE inhibitor during the first three months of pregnancy had an increased risk of birth defects when compared with babies whose mothers did not take any drugs for high blood pressure.
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The FDA has urged healthcare providers to take this information into account when prescribing one of these drugs for women of childbearing age. The FDA has also reiterated the need for providers to discontinue an ACE inhibitor as soon as possible if a patient taking one of these drugs becomes pregnant.

A Further Thought: Since 50 percent of all pregnancies in this country are unplanned, and since a newly pregnant woman may be far along in her first trimester before she’s seen for her first checkup, it may be prudent not to prescribe an ACE inhibitor for women of childbearing age at all.

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