

THE PROBLEM THAT WON'T QUIT ■

So what's a troubled pain sufferer to do?

Well, if you're routinely taking Darvon (or any of the other propoxyphene drugs) for everyday aches or pains, and you've been taking it for some time, you might look seriously at giving it up—or at least talking over your situation with a physician.

If you've been prescribed propoxyphene for a brand-new pain, take the drug only as directed and stop at your first opportunity.

And if you're taking Darvon because you're addicted to it (or think you might be), contact a local drug treatment facility to get some help for yourself.

Because in spite of all the lumps it's taken, Darvon is still all too capable of inflicting a few lumps of its own, particularly to people who don't know what they're dealing with.

And while ignorance about some things can be bliss, with a drug as potentially dangerous as Darvon, ignorance is only ignorance.

And, sometimes, it's deadly. ■



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a CURE WORSE than the disease?

■ ■ ■ a do it now foundation publication by jim parker

Darvon sure has been taking its lumps lately.

Oh, things were fine for a while, and Darvon, which was introduced in the United States in 1957, kept plugging along, year after year, near the top of the list of most-prescribed medications.

For almost two decades, it ranked right behind Valium® and Librium® as one of America's most popular prescription drugs, averaging 39 million prescriptions a year between 1973 and 1975. Then things began to go sour.



Bad sport. Propoxyphene is often used to relieve the strains and sprains of sports injuries.

It started when propoxyphene (the generic name for Darvon®) was cited in 589 overdose deaths in 23 U.S. cities. This led the Ralph Nader-affiliated Health Research Group to demand a federal ban on use of the painkiller.

Calling it “the deadliest prescription drug in the United States,” the group argued that propoxyphene figures into thousands of deaths and medical emergencies each year—many of them accidental overdoses.

It continued when the 1989 Darvon-related death of former NFL great John Matuszak prompted the group to renew its demand for removal of the drug from the U.S. market.

Somewhere in between, the U.S. Food and Drug Administration stepped in, setting new guidelines for how and when and for how long doctors could prescribe the drug.

So what's everybody got against Darvon, anyway? And why, in spite of a lot of people's best efforts, won't it (and other propoxyphene-based drugs like it) go away?

LUMPS



Even its own manufacturer admitted that there is “no substantial evidence to demonstrate that 65mg of Darvon is more effective than 650mg of aspirin...”



Good questions.

But to answer them fully we first have to look closely at the make-up and properties of the drug itself: the chemical propoxyphene.

WHAT IT IS, WHAT IT ISN'T ■

So what *is* propoxyphene?

Structurally, it's related to the synthetic narcotic, methadone. It's prescribed in two forms—propoxyphene hydrochloride and propoxyphene napsylate—for relief of mild to moderate pain.

Aside from slight differences—the napsylate (or N-form) of propoxyphene is more slowly absorbed in the body and so has a longer duration of action—the two drugs are identical. Both are found in a number of prescription pain medications, including:

- ▶ Darvon® and Darvon-N® (propoxyphene only)
- ▶ Darvon with A.S.A.®, Darvon-N with A.S.A.® (with aspirin)
- ▶ Darvocet®, Darvocet-N®, Wygesic® (with acetaminophen)
- ▶ Darvon Compound®, Darvon Compound-65® (with aspirin and caffeine)

But in whatever form, propoxyphene is prescribed and sold as a mild analgesic for pain that won't stop with aspirin.

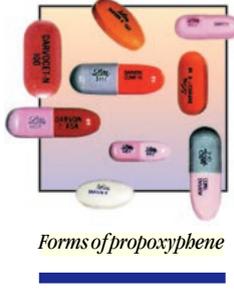
So why all the fuss?

For one thing, Darvon doesn't work—at least not as well as it was supposed to.

When it was introduced back in 1957, its manufacturer, Eli Lilly and Company, promoted it as a safe, non-addicting substitute for codeine.

But the closer people looked, the less Darvon looked like a safe, non-addicting substitute for anything. In fact, in 1972, after clinical studies questioned propoxyphene's effectiveness as a pain reliever, Lilly had to release a statement backing off some of its earlier claims on behalf of the drug.

Acknowledging that "the preponderance of evidence indicates that it may be somewhat less potent than codeine," Lilly even conceded in its retraction there was "no substantial evidence to demonstrate that 65mg of Darvon is more effective than 650mg of aspirin [two standard tablets]."



Forms of propoxyphene

No more effective than aspirin? Some authorities, including the American Medical Association's *Drug Evaluations*, went a step further, arguing that a dose of propoxyphene is actually *less* effective than a normal dose of aspirin.

Okay, so if propoxyphene is less effective and less potent than codeine and no better than two aspirin in relieving pain, what good is it, anyway?

Another good question, and one that gets more interesting the closer you get to the serious hazards associated with propoxyphene.

RISKS & REALITIES ■

When people run into problems with propoxyphene, it's often due in large part to the drug's ineffectiveness.

Since it's most often prescribed for relief of pain, propoxyphene can easily be misused—particularly when relief does not appear to be fast or forthcoming. But pain sufferers who self-prescribe a double dose of Darvon when a first dose fails may be writing themselves a prescription for trouble.

Propoxyphene overdoses are double trouble—and often deadly—because they happen so quickly...

Reasons revolve around unusual properties of the drug itself.

For one thing, the gap between a therapeutic dose and an overdose is small. This margin of safety is so slight, in fact, that as little as four times the standard dose can trigger a dangerous slowing of breathing and heart rate. Six times a therapeutic dose can cause seizures and symptoms of toxic psychosis.

Darvon's small safety margin shrinks further if the drug is taken with alcohol or other depressants.

In fact, more than 93 percent of all propoxyphene-related deaths in a single recent year were the result

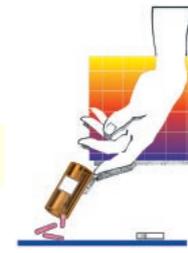
of interactions with other drugs—more than half involving alcohol or diazepam. (Valium®).

ADDICTION AND RISKS ■

Given propoxyphene's similarities to methadone, it's not surprising that the drug is as addictive as it is.

In fact, the medical journal *Clinical Pharmacology* even argued that propoxyphene's "most prominent effect...may be its addictive quality."

And that danger hasn't been lost on a generation of users, either.



Rx: PRESCRIPTION NARCOTICS

A number of Darvon-like natural and synthetic narcotics are widely used as pain relievers today. When used properly, these drugs can mean the difference between incapacitating pain and normal functioning. But when overused or used improperly, they can produce the same problems as propoxyphene: overdose, addiction, and other health risks.

The most common side effects of the prescription pain relievers listed below are a group of symptoms that include dizziness, sedation, and nausea or vomiting. Other effects include flushing or tingling of the skin, dry mouth, lethargy, impaired concentration, and constipation. Like propoxyphene, all produce varying degrees of physical and psychological dependence. Each also produces tolerance, or a need to boost dosage in order to achieve similar effects.

Although the drugs have a broad range of effects and abuse potential, they share one thing in common: a nasty overdose syndrome that can be life threatening. Symptoms of overdose include pinpoint pupils, muscle flaccidity, depression of breathing and heart rate, stupor, and coma. Medical intervention is essential.

Probably the best advice to follow with all prescription narcotics is to take them with a healthy dose of caution. Because while their effects—and dangers—can range from very mild to very severe, they all can take away something infinitely more important than pain when used incorrectly. And they can all be used incorrectly.

DRUG NAME	TRADE NAME(S)	OTHER DRUGS PRESENT	PHYSICAL DEPENDENCE	PSYCHOLOGICAL DEPENDENCE
Codeine	Tylenol® #1,2,3,4	Acetaminophen	Low	Moderate
	Empirin® #1,2,3,4	Aspirin		
Oxycodone	Percodan®	Aspirin	High	High
	Percocet®	Acetaminophen		
Hydromorphone	Dilaudid®	—	High	High
Meperidine	Demerol®	—	High	High
Pentazocine	Talwin-50®	Naloxone	Low-Moderate	Moderate-High
	Talwin-NX®			

Darvon produces psychological and physical dependence like other narcotics, and treatment for Darvon dependence is much the same, too.

Other risks are tied to substances often found in propoxyphene preparations. Aspirin and acetaminophen are particularly dangerous since they can damage the liver and kidneys when overused.

Similarly, heavy doses of caffeine (found in Darvon Compound® and Darvon Compound-65®) can cause jitteriness, insomnia, and anxiety—which some users relieve by taking tranquilizers or sleeping pills, which further compounds the risk of overdose.

That brings us to a final danger of Darvon that's confronted too many users over the years: a potentially-fatal overdose syndrome.

Symptoms are similar to other narcotics overdoses, and include convulsions, stupor, pinpoint pupils, respiratory depression, and coma.

But propoxyphene overdoses are double trouble—and often deadly—because they happen so quickly. In fact, one study has shown that 20 percent of fatal overdoses occur in the first hour after ingestion of the drug.

Due to the seriousness of a propoxyphene OD and the rapid onset of symptoms, medical help should be sought immediately.

DARVON TODAY ■

Given the lumps that Darvon's been taking lately, it would seem to follow that propoxyphene would almost have disappeared as a drug problem by now, right?

Not quite. Because propoxyphene figured into an estimated 5,625 emergency room admissions nationwide in 2008. And, according to the advocacy group Public Citizen, a main reason is that the drug breaks down in the body into a metabolite that's even more toxic (and longer-acting) than propoxyphene itself.

And that means potential trouble for everyone who takes it.

