

Palladone™ and Duragesic® Warnings

Palladone™ (extended-release hydromorphone)

We alerted you to the potential for abuse of Palladone™ (extended-release hydromorphone) in the May 2005 Toxtidbits. As of July 13, 2005, sales and marketing of Palladone™ have been suspended. A recent pharmacokinetic study showed that co-ingestion of a 12 mg Palladone™ capsule with 8 ounces of 40% (80 proof) alcohol resulted in an average peak hydromorphone concentration six times greater than when taken with water. In some subjects, ingestion of 8 ounces of 4% alcohol (about 2/3 of a typical serving of beer) resulted in almost twice the peak plasma hydromorphone concentration than when taken with water. Alcohol disturbs the extended-release mechanism leading to "dose-dumping", a rapid release of the active ingredient from an extended-release formulation. This withdrawal is not a recall so existing Palladone™ stocks may still be available. The FDA is advising that patients switch to an alternate analgesic, but some might continue to take their remaining supply. All patients currently taking Palladone™ should be immediately contacted and warned to avoid drinking any alcohol. Patients exhibiting signs and symptoms of an opioid overdose (lethargy, coma, respiratory depression, pinpoint pupils) due to the co-ingestion of Palladone™ with alcohol should be treated with supportive care and naloxone if needed. Keep in mind that naloxone might induce withdrawal in a patient who has been chronically taking this drug or another opioid.

Duragesic® (fentanyl) transdermal patch

The FDA issued a warning on July 15, 2005 concerning reports of presumed unintentional overdose deaths in patients using Duragesic® (fentanyl) patches. Possible causes include use of high doses and/or multiple patches, medication errors, unintentional contact with a discarded patch, application of heat to the patch, injection or ingestion of the patch contents, and suspected leaking patches. Fentanyl is a potent opioid analgesic. The directions for use of Duragesic® patches must be followed exactly to prevent serious opioid effects and death.

DID YOU KNOW THAT... The FDA warns that a dietary supplement called Liqiang 4, has been found to contain glyburide?

Glyburide is a sulfonylurea used in diabetics to lower blood glucose. Ingestion of glyburide in children, patients being treated with diabetes drugs, or patients with low blood glucose can result in severe and prolonged hypoglycemia. Liqiang 4 is sold in herbal stores and through mail order. Chinese language ads promote it for diabetes and state that it is derived from natural ingredients.



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