ToxTidbits

Maryland Poison Center
UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY

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The Maryland Poison Center's Monthly Update: News, Advances, Information

Zohydro™ ER (Hydrocodone)

Zohydro ER is the first single ingredient, extended-release hydrocodone product approved by the FDA. It is expected to appear on pharmacy shelves in March 2014. Zohydro ER is indicated for the management of severe pain requiring daily, around-the-clock, long-term opioid treatment and for which alternative options (non-opioid analgesics or immediate release opioids) are inadequate. Zohydro ER differs from other prescription hydrocodone products in that it does not contain acetaminophen, ibuprofen or other pharmaceuticals. It will be available as 10 mg, 15 mg, 20 mg, 30 mg, 40 mg and 50 mg capsules. In contrast, immediate release formulations of hydrocodone in combination with acetaminophen (e.g. Vicodin) come in dosage strengths of 5 mg, 7.5 mg and 10 mg.

The availability of this hydrocodone formulation has been met with some criticism and concerns that misuse of the drug will lead to abuse, dependence and overdose deaths. Unlike OxyContin® (oxycodone controlled release), Zohydro ER is not formulated with an abuse deterrent. As a result, it can be crushed, chewed or dissolved to bypass the extended release mechanism, allowing the user to feel the full affect of the dose in a short time versus over twelve hours. The attorneys general from twenty-eight states have asked the FDA to review and reconsider the approval of Zohydro ER.

The FDA is requiring postmarketing studies of Zohydro ER to assess the risks of misuse, hyperalgesia, addiction and overdose associated with use for longer than twelve weeks. Zogenix, the company releasing Zohydro, has announced the formation of an External Safe-Use Board to review data about the drug's prescribing and use and, if necessary, "to recommend specific actions needed to ensure that the risk of abuse, misuse and diversion is minimized."

Overdoses of Zohydro ER would be expected to present with the same toxic effects seen with other opioids: lethargy, coma, constricted pupils, and respiratory depression. Treatment of hydrocodone toxicity consists of supportive care and the use of naloxone.

Urine drug screens may be positive for opiates when hydrocodone has been taken, but false negatives may occur, depending on the amount of hydrocodone present and the immunoassay utilized. Because hydrocodone is metabolized to hydromorphone, specific drug identification tests performed to confirm results (e.g. gas chromatography-mass spectroscopy) may be positive for both drugs.

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Did you know?

March 16-22, 2014 is National Poison Prevention Week (NPPW).

Poison centers and health care providers throughout the U.S. use this week to highlight the dangers of poisons, how to prevent poisonings in people of all ages, and what action to take if a poisoning occurs. Join us in promoting National Poison Prevention Week! Visit our website at www.mdpoison.com to learn more about poisonings and to obtain materials for displays and distribution to patients and families. Also on our website are downloadable videos, games, and activity sheets for all ages.