



Proven Solutions for Cost Containment

Pharmacy

Medical Services
and Equipment

Settlement Solutions

Extended-Release Hydrocodone (Zohydro®) (possible 2013 availability)

NOTICE

Zogenix, a specialty pharmaceutical company based out of San Diego, California, has announced its plans to tentatively apply for 2013 FDA approval to market its version of an extended-release formulation of hydrocodone, Zohydro®. The introduction of this agent may represent the availability of the first hydrocodone product, not in combination with another ingredient, into the U.S. market.

BACKGROUND

Currently available only in combination products such as Vicodin® (hydrocodone-acetaminophen) and Vicoprofen® (hydrocodone-ibuprofen), hydrocodone is an opioid pain reliever used for the relief of moderate to severe pain. Unlike various other opioid pain relievers which are available as stand-alone (not in combination with another product) short and long-acting formulations, an extended-release version of hydrocodone has not been available to patients thus far. Among various pharmaceutical manufacturers currently conducting clinical trials of an extended-release formulation of hydrocodone, Zogenix of San Diego, California indicates that it may be ready to apply for FDA approval of its extended-release hydrocodone product, Zohydro, as early as 2013. A likely driver for the new development efforts related to hydrocodone is the January 2011 mandate by the FDA for dosage limitations for combination opioid-acetaminophen products to contain no more than 325 mg of acetaminophen per dose in response to concerns for medication-related liver toxicity. While the FDA's mandate describes a phased discontinuation of these products to conclude in early 2014, drug manufacturers appear eager to bring the first hydrocodone mono-product to market in time for this deadline. Although the FDA has not yet formally approved an immediate or extended-release hydrocodone mono-product, it is expected that manufacturers will continue to bring new or modified opioid drug products to market as the deadline for FDA dosage limitations on acetaminophen draws closer. While many critics continue to warn that the introduction of these agents may likely lead to an increase in the abuse potential of opioid pain relievers, it is expected that appropriate patient selection and prescribing will help to limit their abuse potential and ensure that these agents are used in the course of accepted medical purposes in a legitimate manner..

RECOMMENDED ACTIONS

Currently, hydrocodone products are only commercially available in combination with non-opioid constituents, such as acetaminophen and ibuprofen; therefore, no action is required or anticipated at this time. Although the public's focus on hydrocodone mono-products appears to be growing, it is likely that the pain management prescriber community will view the availability of products such as Zohydro as another treatment option in the face of declining availability of combination opioid products. Like all opioids, safe prescribing of Zohydro requires diligent adherence to recommended pain management guidelines for patient selection and monitoring in order to avoid deleterious health outcomes.

Reference: Zohydro (hydrocodone bitartrate) extended-release capsules. Zogenix. <http://www.zogenix.com/index.php/products/zx002/> <Accessed January 4, 2012>

DISCLAIMER

This publication is provided as reference material and is based in part on information derived from third parties. PMSI does not assume liability or responsibility for the accuracy or completeness of any third-party material in this document. The information contained herein should not be construed as an endorsement of any kind. This document is advisory in nature only and does not replace sound clinical judgment or individualized patient care in the delivery of drug therapy.

PMSI — Proven Solutions for Cost Containment. In 1976, PMSI is a leader in developing solutions to control the growth of medical costs in workers' compensation. As one of the nation's largest and most experienced companies focused solely on workers' compensation, we deliver proven solutions for cost containment across the claims lifecycle. PMSI's Pharmacy, Medical Services and Equipment, and Settlement Solutions products deliver quantifiable results and improve the quality of care for injured workers. We provide our customers with the innovation, focus, expertise, analytics and technology needed to successfully deliver workers' compensation benefits.