FDA News Release

FDA approves extended-release, single-entity hydrocodone product with abuse-deterrent properties

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Release

The U.S. Food and Drug Administration today approved Hysingla ER (hydrocodone bitartrate), an extended-release (ER) opioid analgesic to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Hysingla ER has approved labeling describing the product’s abuse-deterrent properties consistent with the FDA’s 2013 draft guidance for industry, Abuse-Deterrent Opioids – Evaluation and Labeling (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf).

Hysingla ER has properties that are expected to reduce, but not totally prevent, abuse of the drug when chewed and then taken orally, or crushed and snorted or injected. The tablet is difficult to crush, break or dissolve. It also forms a viscous hydrogel (thick gel) and cannot be easily prepared for injection. The FDA has determined that the physical and chemical properties of Hysingla ER
are expected to make abuse by these routes difficult. However, abuse of Hysingla ER by these routes is still possible. It is important to note that taking too much Hysingla ER, whether by intentional abuse or by accident, can cause an overdose that may result in death.

“While the science of abuse deterrence is still evolving, the development of opioids that are harder to abuse is helpful in addressing the public health crisis of prescription drug abuse in the U.S.,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research. “Preventing prescription opioid abuse is a top public health priority for the FDA, and encouraging the development of opioids with abuse-deterrent properties is just one component of a broader approach to reducing abuse and misuse, and will better enable the agency to balance addressing this problem with ensuring that patients have access to appropriate treatments for pain.”

Hysingla ER is not approved for, and should not be used for, as-needed pain relief. Given Hysingla ER’s risks for abuse, misuse and addiction, it should only be prescribed to people for whom alternative treatment options are ineffective, not tolerated or would be otherwise inadequate to provide sufficient pain management. As a single-entity opioid, Hysingla ER does not carry the serious liver toxicity risks associated with hydrocodone combination products containing acetaminophen. The FDA encourages health care professionals to review and consider all available information as part of their decision-making when prescribing opioid analgesics.

Strengths of Hysingla ER contain 20, 30, 40, 60, 80, 100 and 120 milligrams (mg) of hydrocodone to be taken every 24 hours. Doses of 80 mg per day and higher should not be prescribed to people who have not previously taken an opioid medication (opioid non-tolerant). While Hysingla ER contains larger amounts of hydrocodone compared to immediate-release hydrocodone combination products, the range of tablet strengths of Hysingla ER is comparable to existing approved ER opioids.

The safety and effectiveness of Hysingla ER were evaluated in a clinical trial of 905 people with chronic low back pain. Additional data from studies conducted in laboratories and in people demonstrated the abuse-deterrent features of Hysingla ER for certain types of abuse (oral, snorting and injection). The most common side effects of Hysingla ER are constipation, nausea, fatigue, upper respiratory tract infection, dizziness, headache and drowsiness (somnolence).
The FDA is requiring postmarketing studies of Hysingla ER to assess the effects of the abuse-deterrent features on the risk for abuse of Hysingla ER and the consequences of that abuse in the community. In addition, Hysingla ER is part of the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), which requires companies to make available to health care professionals educational programs on how to safely prescribe ER/LA opioid analgesics and to provide Medication Guides and patient counseling documents containing information on the safe use, storage, and disposal of ER/LA opioids.

Hysingla ER is manufactured by Stamford-based Purdue Pharma L.P.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

✉️ **Jeff Ventura (mailto:jeff.ventura@fda.hhs.gov)**

📞 301-796-7567

Consumers

📞 888-INFO-FDA

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