

FDA Approves New Opioid Hysingla ER



The FDA has approved a new opioid with properties that make it difficult to abuse. Hysingla ER (hydrocodone bitartrate) is an extended-release opioid analgesic which is designed to treat severe pain that requires around-the-clock, long-term treatment.

Drug overdose is a major problem in the US and deaths from overdosing have been rising consistently over the last two decades. Drug overdose is one of the leading causes of injury death. Data from the CDC indicates that 114 people in the US die every day from a drug overdose, while 6,758 are treated in emergency rooms for abuse or misuse of drugs.

According to Dr. Janet Woodcock, 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."

The new opioid, Hysingla ER, is difficult to abuse because the tablet cannot be crushed, broken or dissolved easily. In addition, the drug forms a thick gel making it difficult to be prepared for injection. The labelling for the drug is also consistent with the 2013 draft guidance for the industry and describes the product's abuse-deterrent properties.

The drug is available in strengths of 20, 30, 40, 60, 80, 100 and 120 mg, to be taken every 24 hours. Doses of 80 mg or higher are not recommended for individuals who have not previously taken an opioid medication. The FDA says that the range of tablet strengths for the drug is comparable to existing approved opioids.

Hysingla ER is also not associated with liver toxicity risks that have generally been seen with other hydrocodone combination drugs that contain acetaminophen. A clinical trial with 905 patients suffering from chronic low back pain assessed the safety and effectiveness of the drug. The results were favourable and showcase the abuse-deterrent properties of Hysingla ER either by oral, snorting or injection routes. Some of the side effects that may be associated with Hysingla ER include constipation, nausea, fatigue, upper respiratory tract infection, dizziness, headache and drowsiness.

While the drug may be difficult to abuse, the FDA does point out that nothing can totally prevent abuse of the drug. If an individual consumes too much Hysingla ER, either intentionally or accidentally, it could still result in an overdose or death. However, the new opioid is still less risky than others and should only be prescribed to patients who find alternative treatment options to be ineffective.

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