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FDA approves tough-to-abuse formulation of oxycodone

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Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride extended release) has been approved by the U.S. Food and Drug Administration as a long-term, around-the-clock treatment for severe pain when other therapies are ineffective or unavailable.

(HealthDay)—Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride extended release) has been approved by the U.S. Food and Drug Administration as a long-term, around-the-clock treatment for severe pain when other therapies are ineffective or unavailable.

Targiniq ER has properties that are designed to deter abuse of the drug by snorting or injection, the FDA said in a news release. It contains naloxone, designed to block the euphoric effects of oxycodone, the agency said. Targiniq ER can still be abused by taking too many pills, the FDA warned, stressing that an overdose could cause death. The drug is not meant for as-needed pain relief, the agency said, repeating its warning of the potential for abuse and addiction.

Targiniq ER was evaluated in a clinical study of 601 people with chronic lower back pain. The most common side effects were nausea and vomiting.

The agency said it is requiring the manufacturer to conduct additional post-marketing studies to assess the drug's risks of misuse, addiction, and abuse.

Targiniq ER is manufactured by Purdue Pharma, based in Stamford, Conn.

More information: More Information