

Xtampza® ER (oxycodone) - Label updates

- On November 7, 2017, <u>Collegium Pharmaceuticals announced</u> the FDA approval of updates to the <u>Xtampza ER (oxycodone)</u> drug label regarding data from pharmacokinetic and human abuse potential studies, along with support from *in vitro* data, indicating that Xtampza ER has physicochemical properties that are expected to reduce abuse via the oral and intranasal routes.
 - However, abuse of Xtampza ER by injection and by the oral and nasal routes of administration is still possible.
- Xtampza ER is indicated for the management of pain severe enough to require daily, around-theclock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Xtampza ER carries a boxed warning for addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 interaction; and risks from concomitant use with benzodiazepines or other CNS depressants.



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