



Title:	Diversion and Illicit Sale of Extended Release Tapentadol in the United States
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Abstract:

Purpose: Prescription opioid analgesics are commonly prescribed for moderate to severe pain. The therapeutic use of prescription analgesics has increased substantially over the last two decades and, in parallel, the abuse and diversion of these medications to the illicit market have also increased. Tapentadol is a recently approved centrally acting opioid analgesic with two synergistic mechanisms of action: μ -opioid receptor agonism and inhibition of norepinephrine re-uptake. The immediate release (IR) form of tapentadol (Nucynta®, Janssen Pharmaceuticals, Inc.) was introduced in 2009. The extended release (ER) formulation was approved in 2012 and is available as Nucynta ER® (Janssen Pharmaceuticals, Inc.) In the United States, the ER product utilizes a proprietary crush-resistant formulation. We compared rates of diversion events and related cost of obtaining tapentadol IR and tapentadol ER as well as other Schedule II opioid medications in street transactions in the United States.

Results: The average quarterly diversion rates were 0.003 for tapentadol IR, 0.0004 for tapentadol ER, and 1.54 for other Schedule II opioid tablets per 100,000 population. The tapentadol ER rate was significantly lower than the other Schedule II opioid tablets ($p < 0.0001$) and tapentadol IR ($p = 0.0015$). Rates based on drug availability were 0.043 for tapentadol IR, 0.018 for tapentadol ER, and 0.285 for other Schedule II opioid tablets per 1,000 prescriptions dispensed. The tapentadol ER prescriptions dispensed rate was significantly less than the other Schedule II opioid prescriptions dispensed rate (adjusted $p = 0.0003$) but similar to tapentadol IR (adjusted $p = 0.41$). The median street price per milligram was \$0.16 (tapentadol IR), \$0.10 (tapentadol ER), and \$1.00 (other Schedule II opioid tablets).

Conclusions: Our results indicate that tapentadol ER, which utilizes a proprietary crush-resistant formulation, is rarely sold illicitly in the United States. In the two years since its introduction, diversion rates for tapentadol ER have remained low despite the increased number of prescriptions for the drug. In contrast, illicit distribution of other Schedule II opioids is much higher and has persisted for

many years. Further, the black market price of tapentadol ER is low, particularly in comparison to prices for other Schedule II opioids.