



OXYCODONE

(Trade Names: Tylox®, Percodan®, OxyContin®)

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DEA/OD/ODE

Introduction:

Oxycodone is a schedule II narcotic analgesic and is widely used in clinical medicine. It is marketed either alone as controlled release (OxyContin®) and immediate release formulations (OxyIR®, OxyFast®), or in combination with other nonnarcotic analgesics such as aspirin (Percodan®) or acetaminophen (Percocet®). The introduction in 1996 of OxyContin®, commonly known on the street as OC, OX, Oxy, Oxycotton, Hillbilly heroin, and kicker, led to a marked escalation of its abuse as reported by drug abuse treatment centers, law enforcement personnel, and health care professionals. Although the diversion and abuse of OxyContin® appeared initially in the eastern U.S., it has now spread to the western U.S. including Alaska and Hawaii. Oxycodone-related adverse health effects increased markedly in recent years. In 2004, Food and Drug Administration (FDA) approved generic forms of controlled release oxycodone products for marketing.

Licit Uses:

Products containing oxycodone in combination with aspirin or acetaminophen are used for the relief of moderate to moderately severe pain. Oxycodone controlled-release tablets are prescribed for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. Oxycodone is widely prescribed in the U.S. In 2010, 58.2 million oxycodone prescriptions were dispensed and 15.0 million in the first quarter of 2011 (IMS Health™). In 2011, the aggregate production quota for oxycodone was 105,500 kilograms.

Chemistry/Pharmacology:

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone will test positive for an opiate in the available field test kits. Pharmacology of oxycodone is essentially similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, sedation, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. A 10 mg dose of orally-administered oxycodone is equivalent to a 10 mg dose of subcutaneously administered morphine as an analgesic in the normal population. Oxycodone's behavioral effects can last up to 5 hours. The drug is most often administered orally. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours). As with most opiates, oxycodone abuse may lead to dependence and tolerance. Acute overdose of oxycodone can produce severe respiratory depression, skeletal muscle flaccidity, cold and clammy skin, reduction in blood pressure and heart rate, coma, respiratory arrest, and death.

Illicit Uses:

Oxycodone abuse has been a continuing problem in the U.S. since the early 1960s. Oxycodone is abused for its euphoric effects. It is equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) administration.

For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The large amount of oxycodone (10 to 80 mg) present in controlled release formulations (OxyContin®) renders these products highly attractive to opioid abusers and doctor-shoppers. They are abused either as intact tablets or by crushing

or chewing the tablet and then swallowing, snorting or injecting. Products containing oxycodone in combination with acetaminophen or aspirin are abused orally. Acetaminophen present in the combination products poses an additional risk of liver toxicity upon chronic abuse.

The 2009 National Survey on Drug Use and Health (NSDUH) indicated that 15.3 million people, aged 12 and older in the U.S., used oxycodone products nonmedically in their lifetime. According to the American Association of Poison Control Centers (AAPCC), there were 18,396 exposures (8,721 single substance exposures) and 25 deaths associated with oxycodone in 2009. The 2010 Monitoring the Future survey indicates that 2.1% of 8th graders, 4.6% of 10th graders and 5.1% of 12th graders misused OxyContin® in the past year. In 2009, there were an estimated 148,449 emergency department visits related to nonmedical use of oxycodone, according to the Drug Abuse Warning Network (DAWN ED), a significant increase from 105,214 visits in 2008.

User Population:

Every age-group has been affected by the relative prevalence of oxycodone availability and the perceived safety of oxycodone products by professionals. Sometimes seen as a "white-collar" addiction, oxycodone abuse has increased among all ethnic and economic groups.

Illicit Distribution:

Oxycodone-containing products are in tablet, capsule, and liquid forms. A variety of colors, markings, and packaging are available. The main sources of oxycodone on the street have been through forged prescriptions, professional diversion through some pharmacists, doctors, and dentists, "doctor-shopping," armed robberies, and night break-ins of pharmacies and nursing homes. The diversion and abuse of OxyContin® has become a major public health problem in recent years. According to reports from DEA field offices, oxycodone products sell at an average price of \$1 per milligram, the 40 mg OxyContin® tablet being the most popular. In 2009, oxycodone became the most frequently encountered pharmaceutical drug by law enforcement, with 46,538 items/exhibits identified as oxycodone in 2009 by federal, state and local forensic laboratories in the United States. In 2010, the number of items/exhibits increased by 28% to 59,614. There were 13,673 items/exhibits identified by forensic laboratories as oxycodone in the first quarter of 2011.

Control Status:

Oxycodone is a schedule II substance under the Controlled Substances Act of 1970. Massachusetts proposed that any preparation of oxycodone manufactured to delay absorption into the blood system, unless it contains one or more active non-narcotic ingredients, shall be in schedule I. Massachusetts also proposed to add oxycodone as a Class A controlled substance. Pennsylvania proposed to add OxyContin® as a schedule I drug.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 202-353-1263, telephone 202-307-7183, and Email ODE@usdoj.gov.