

April 2023

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

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®). In 2004, the Food and Drug Administration (FDA) approved generic forms of controlled release oxycodone products for marketing. 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.

Licit Uses:

Products containing oxycodone in combination with aspirin or acetaminophen are used for the relief of moderate to moderately severe pain. Oxycodone is widely prescribed in the U.S., and the 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.

According to IQVIA National Prescription Audit[™], total prescriptions dispensed for oxycodone were approximately 48.7 million in 2018, 45.1 million in 2019, 42.5 million in 2020, and 42.7 million in 2021.

Chemistry:

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid receptor agonist derived from thebaine, a constituent of opium. Oxycodone will test positive for an opiate in the available field test kits.

Pharmacology:

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. Behavioral effects of oxycodone 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 National Survey on Drug Use and Health (NSDUH) indicated that in 2019 1.2 % (or 3.2 million people) misused oxycodone products that year. Similar to 2019, in 2020 1.1 % (or 3.2 million people) misused oxycodone products. However, caution should be used when comparing estimates between 2020 and prior years because of methodological changes for 2020. In 2021, 12.8 % misused oxycodone products. According to the American Association of Poison Control Centers (AAPCC), in 2020, there were 7,188 case mentions (3,433 single exposures) and 16 deaths with oxycodone alone or in combination. In 2021 the AAPCC reported 6,816 case mentions (3,218 single exposures) and 17 deaths with oxycodone alone or in combination. The 2020 Monitoring the Future (MTF) survey indicates that the annual prevalence in 2020 was 0.9%, 1.0%, and 2.4% in grades 8, 10, and 12, respectively for the misuse of OxyContin[®]. The 2021 Monitoring the Future (MTF) survey indicates that the annual prevalence in misuse of OxyContin® has decreased since 2020 from 0.9% to 0.8%, 1.9% to 0.9%, 2.4% to 0.9% in grades 8, 10 and 12, respectively.

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, physicians, dentists, "doctor-shopping," armed robberies, and night break-ins of pharmacies and nursing homes. The diversion and abuse of oxycodone 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. Oxycodone has been the top pharmaceutical drug each year since then. According to DEA's National Forensic Laboratory Information System (NFLIS) Drug database, the annual number of oxycodone reports submitted by participating federal, state and local forensic drug laboratories totaled 23,956 in 2019, 17,210 in 2020,15,474 in 2021, and 10,696 in 2022.

Control Status:

Oxycodone is a schedule II substance under the Controlled Substances Act.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 571-362-4250, Telephone 571-362-3249, and Email <u>DPE@dea.gov.</u>