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DEA/DC/DOE

Oxymorphone

(Trade Names: Opana®, Opana ER®; Street Names: Blue Heaven, Blues, Mrs. O, New Blues, Octagons, Oranges, Orgasna IR, OM, Pink, Pink Heaven, Pink Lady, Pink O, Stop Signs, and The O Bomb)

Introduction:

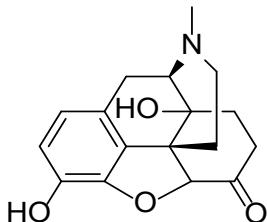
Oxymorphone (14-hydroxydihydromorphinone) is a potent schedule II opioid analgesic drug with an abuse liability similar to morphine and other schedule II opioids. It was first marketed in the United States for medical use in 1959 in injectable and rectal suppository forms. The Food and Drug Administration (FDA) approved immediate-release (IR) and extended-release (ER) oxymorphone oral tablets under brand names Opana® and Opana ER® in 2006 with generic version getting final approval in 2010. However, Opana ER® was discontinued in 2017, due to its public health risks from abuse outweighed its benefits.

Licit Uses:

Oxymorphone is indicated for the relief of moderate to severe pain. It is currently marketed both as immediate release tablets containing 5 mg or 10 mg and as extended-release tablets containing 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, or 40 mg oxymorphone hydrochloride. According to IQVIA's National Prescription Audit™, total prescriptions dispensed in the United States for all products containing oxymorphone were approximately 1.01 million 2010, 1.24 million in 2015, 240,000 in 2020, and 60,000 in 2024.

Chemistry:

Chemically, oxymorphone is 4,5α-epoxy-3,14-dihydroxy-17-methylmorphinan-6-one. It is commonly found as its hydrochloride salt, an odorless, white or slightly off-white powder that is freely soluble in water, but sparingly soluble in alcohol and ether.



Pharmacology:

Oxymorphone is a opioid agonist that is selective for the *mu* opioid receptor. However, at higher doses, it can interact with other opioid receptors. Similar to other opioid analgesics, with increasing doses of oxymorphone, there is increasing analgesia effects. Pharmacological and toxic effects, abuse, and dependence liabilities of oxymorphone are essentially similar to other schedule II opioid analgesics, such as morphine and oxycodone.

In addition to analgesia, other pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis and cough suppression. Use of oxymorphone, like other schedule II opioid analgesics, carries the risk of addiction, physical dependence and/or tolerance. Abrupt discontinuation after prolonged use can cause signs and symptoms of opioid withdrawal.

Acute overdose of oxymorphone, similar to other opioid agonist analgesics, can produce severe respiratory depression, somnolence (drowsiness) progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and reduction in blood pressure and heart rate. In some cases, acute overdose may result in apnea, circulatory collapse, cardiac arrest, and death. The use of an opioid receptor antagonist such as naloxone acts as a specific antidote against respiratory depression resulting from overdose or unusual sensitivity to oxymorphone.

Illicit Uses:

Oxymorphone products, similar to other schedule II opioids, have high abuse and dependence potential, produce tolerance, and are abused for their euphoric effects. Snorting, oral ingestion, and injection are some reported routes of administration. Abuse, or misuse of oxymorphone tablets by crushing, chewing, snorting, or injecting the dissolved products will result in the uncontrolled delivery of the oxymorphone and can result in overdose and death. Demographics of oxymorphone abuser population are similar to those of other opioid analgesics and mainly include young Caucasian adults. The America's Poison Centers reported 89 total oxymorphone exposures, 38 single exposures, and one death in 2020, a decrease from 91 total case exposures (single exposures of 44) but zero deaths in 2019.

User Population:

Every demographic has been affected by oxymorphone availability. Initially, abuse of oxymorphone was most prevalent among young, Caucasian adults, but it has expanded to include other groups, such as non-Hispanic Black and Latino people.

Illicit Distribution:

Oxymorphone is illicitly available under a variety of street names (see above) in numerous states. Similar to other opioid pharmaceuticals, methods of diversion of oxymorphone products include fraudulent and forged prescriptions, robberies, thefts, and organized polydrug trafficking.

The Drug Enforcement Administration's National Forensic Laboratory Information System (NFLIS) Drug database collects scientifically verified data on drug items and cases submitted to and analyzed by participating federal, state, and local forensic drug laboratories. NFLIS-Drug received 185 reports of oxymorphone in 2021, 164 in 2022, 83 in 2023, and 36 in 2024 (reports still pending). These reports included identification of oxymorphone alone and in combination with other substances.

Control Status:

Oxymorphone is a schedule II controlled 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, or Email: DPE@dea.gov.