



## OXYMORPHONE

(Trade Names: Opana<sup>®</sup>, Opana ER<sup>®</sup>; 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)

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### Introduction:

Oxymorphone (14-hydroxydihydromorphinone) is a potent schedule II opioid analgesic drug with an abuse liability similar to morphine and other schedule II opioids. Recently there has been an increase in the abuse of oxymorphone. It was first marketed in the United States for medical use in 1959 as injectable and rectal suppository forms. In June 2006, Food and Drug Administration (FDA) approved immediate-release (IR) and extended-release (ER) oxymorphone oral tablets under brand names Opana<sup>®</sup> and Opana ER<sup>®</sup>. Recently generic oxymorphone formulations were approved by FDA.

### 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 and 10 mg and as extended release tablets containing 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride. It is also available as 1 mg/mL injectable formulation.

According to IMS Health<sup>™</sup>, total prescriptions dispensed for oxymorphone increased from 268,000 in 2007 to 1.01 million in 2010. In the first quarter of 2011, 325,000 oxymorphone prescriptions were dispensed by retail pharmacies. Aggregate production quota for oxymorphone (for sale) established by DEA for legitimate medical needs increased from 806 kilograms in 2006 to 3,070 kilograms in 2010.

### Chemistry/Pharmacology:

Chemically, oxymorphone is 4,5 $\alpha$ -epoxy-3,14-dihydroxy-17-methylmorphinan-6-one, commonly used as its hydrochloride salt - a white or slightly off-white, odorless powder, which is sparingly soluble in alcohol and ether, but freely soluble in water. Pharmacological and toxic effects and abuse and dependence liabilities of oxymorphone are essentially similar to other schedule II opioid analgesics such as morphine, oxycodone, etc.

Oxymorphone is a pure opioid agonist relatively selective for the mu opioid receptors. However, at higher doses, it can interact with other opioid receptors. The precise mechanism of analgesic action of oxymorphone is unknown. Similar to pure opioid agonist analgesics, with increasing doses of oxymorphone there is increasing analgesia. There is no defined maximum dose; the ceiling to analgesic effectiveness is imposed only by serious side effects.

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, similar to 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 pure opioid agonists, can produce severe respiratory depression, somnolence 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. Opioid receptor antagonist such as naloxone is a specific antidote against respiratory depression resulting from overdose or unusual sensitivity to oxymorphone. Oxymorphone related deaths have been reported in various states. Medical Examiners Commission Reports released by the Florida Department of Law Enforcement (FDLE) indicate that oxymorphone related deaths in Florida increased by more than 242% from 69 in 2008 to 236 in 2009, surpassing opioids such as heroin, fentanyl, and hydromorphone. In the first six months of 2010, 223 deaths were related 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. Demographics of oxymorphone abuser population are similar to those of other opioid analgesics and mainly include young Caucasian adults. According to the Drug Abuse Warning Network (DAWN ED), total estimated emergency department visits related to oxymorphone increased from 855 in 2008 to 2,248 in 2009.

### Illicit Distribution:

Oxymorphone products are illicitly available under a variety of street names (see above) in numerous states. Street prices of oxymorphone products, though vary, generally retail for one dollar per milligram of oxymorphone. Similar to other opioid pharmaceuticals, methods of diversion of oxymorphone products include fraudulent and forged prescriptions, robberies, thefts, and polydrug trafficking organizations. According to DEA's National Forensic Laboratory Information System and the System to Retrieve Information from Drug Evidence databases, analyzed substances identified as oxymorphone by federal, state, and local forensic laboratories increased from 139 in 2008 to 851 in 2010. During the first quarter of 2011, 536 items were identified as oxymorphone.

### Control Status:

Oxymorphone is controlled in schedule II of the federal Controlled Substances Act.

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