

HYDROMORPHONE

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(Trade names: Dilaudid[®], Exalgo[®], Palladone[®]; Street Names: Dust, Juice, Dillies, Smack, D, Footballs)

Introduction:

Hydromorphone is a potent schedule II opioid analgesic drug. Hydromorphone abuse has been a continuing problem in the United States. It is marketed as injectable ampules, multiple dose vials, tablets, and capsules. Hydromorphone is indicated for relief of moderate-to-severe pain. Hydromorphone is marketed under brand names Dilaudid, Exalgo, and Palladone. It is also marketed in generic forms.

Licit Uses:

According to the IQVIA National Prescription Audit[™], total prescriptions dispensed for hydromorphone in the United States were fairly stable between 2012 and 2015, averaging approximately 3.82 million per year, which then decreased each year after to approximately 2.23 million in 2020, 2.16 million in 2022, and 1.92 million in 2024.

Currently approved hydromorphone products include immediate release tablets (2, 4, and 8 mg), extended release tablets and capsules (8, 12, 16, 24, and 32 mg), oral solution (5 mg/5 ml viscous liquid), and ampules in sterile solution for parenteral injection (0.2, 1, 2, 4, and 10 mg/mL, as well as 0.25 mg/0.5 mL and 0.5 mg/0.5 mL) and intramuscular, intravenous, and subcutaneous injections (2 mg/mL).

Chemistry:

Hydromorphone (4,5-epoxy-3-hydroxy-17-methylmor-phinan-6-one) is a semi-synthetic opioid agonist derived from morphine. It will be positively identified as an opiate in the field test kits.

Pharmacology:

Pharmacological and toxic effects, clinical indications and contraindications, and abuse and dependence liabilities of hydromorphone are essentially similar to those of other schedule II opioid analgesics (e.g., morphine, oxycodone). In humans, the doses of 1.3 and 7.5 mg hydromorphone produces analgesia equivalent to that produced by 10 and 30 mg morphine when taken by the intramuscular and oral routes, respectively. The analgesic action of hydromorphone is perceived within 15 and 30 minutes following its administration through injection and oral routes, respectively. The analgesic action usually lasts for more than 5 hours.

Similar to other opioids, hydromorphone produces euphoria, feelings of relaxation, reduced anxiety, respiratory depression, sedation, constipation, papillary constriction, and cough suppression. Acute overdose of hydromorphone can produce severe respiratory depression, somnolence progressing to

stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, reduction in blood pressure and heart rate, and death. Pure opioid antagonists, such as naloxone, are specific antidotes against respiratory depression from hydromorphone overdose.

Illicit Uses:

Hydromorphone, similar to other schedule II opioids, has a high abuse and dependence potential and produces tolerance. Prior to the current popularity of hydrocodone and oxycodone among drug abusers, low dose (2 and 4 mg) immediate release hydromorphone formulations (i.e., Dilaudid) were the leading opioid products for abuse and diversion. Abuse of hydromorphone is mainly among rural and suburban populations.

Illicit Distribution:

The main sources of hydromorphone diversion include forged prescriptions, "doctor-shoppers" of pharmacists and physicians, armed robberies, and robberies of pharmacies and nursing homes. The diversion of Dilaudid has been reported by the Atlanta, Boston, Chicago, Dallas, Detroit, Houston, Los Angeles, New York, San Antonio, St. Louis, and Washington, D.C. Drug Enforcement Administration (DEA) field offices. The 4 mg tablet of Dilaudid is the most common dose reported. The street price has ranged from \$5 to \$80 per tablet, depending on the dose and region.

DEA'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 5,025 reports of hydromorphone in 2013; 2,414 in 2018; 514 in 2023; and 324 in 2024 (reports still pending). In total, NFLIS-Drug received nearly 50,000 reports of hydromorphone since its first report in 1997.

The 2023 National Survey on Drug Use and Health reported that among people aged 12 and older in the United States, approximately 1.268 million (0.5%) used hydromorphone products in 2022 and approximately 1.565 million (0.6%) misused hydromorphone products in 2023.

Control Status:

Hydromorphone is controlled in schedule II of 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.