Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section

HYDROMORPHONE

(Trade name: Dilaudid®; Street Names: Dust, Juice, Smack, D, Footballs)

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DEA/OD/ODE

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 ampoules, multiple dose vials, tablets and suppositories. Hydromorphone is indicated for relief of moderate-to-severe pain. Hydromorphone is marketed under brand names, Dilaudid® and Exalgo®. It is also marketed in generic forms.

Licit Uses:

The total dispensed prescriptions of hydromorphone in the U.S. increased 40%, from 2.5 million in 2008 to 3.5 million in 2011, according to IMS Health®. Aggregate production quota for hydromorphone as established by DEA for legitimate national needs increased from 3,300 kilograms in 2008 to 3,455 kilograms in 2012.

On September 24, 2004, the Food and Drug Administration (FDA) approved for marketing an extended release capsule formulation (Palladone®) containing 12, 16, 24 and 32 mg hydromorphone. Palladone® was indicated for the management of persistent, moderate-to-severe pain. Its use was restricted to opioid-tolerant patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer.

Within 6 months following the launch of Palladone®, new data was provided, by the sponsor of Palladone®, to the FDA showing that drinking alcohol while taking Palladone® may cause rapid release (dose dumping) of hydromorphone, leading to high drug levels in the body, with potentially fatal effects. In view of these new data and at the FDA's request, the sponsor suspended the sales and marketing of Palladone® in July 2005.

Chemistry/Pharmacology:

Hydromorphone, [4,5-epoxy-3-hydroxy-17-methylmorphinan-6-one] is a semi-synthetic opioid agonist derived from morphine. It will be positively identified as an opiate in the field test kits. Pharmacological and toxic effects, clinical indications and contraindications, abuse and dependence liabilities of hydromorphone are essentially similar to those of other schedule II opioid analgesics such as morphine, oxycodone, etc. 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. Palladone®, an extended-release product, which was withdrawn from the market, has a longer duration of action and requires only once-a-day administration. 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. Street names for Dilaudid® are Dust, Juice, Dillies, Smack, D and Footballs. Abuse of hydromorphone is mainly among rural and suburban populations. Emergency department visits associated with hydromorphone increased significantly from an estimated 18,276 in 2007 to an estimated 28,738 in 2009 (DAWN ED).

Illicit Distribution:

The main sources of hydromorphone diversion include forged prescriptions, "doctor-shoppers," unscrupulous pharmacists and physicians, armed robberies, robberies of pharmacies and nursing homes. The diversion of Dilaudid® has been reported by a number of DEA field offices including Atlanta, Boston, Chicago, Dallas, Detroit, Houston, Los Angeles, New York, San Antonio, St. Louis, and Washington D.C. The street price of a 4 mg tablet of Dilaudid®, the most common dosage strength reported, ranges from $5 to $100 per tablet depending on the region. According to DEA's National Forensic Laboratory Information System and System to Retrieve Information from Drug Evidence (STRIDE), there were 2,230, 2,604, and 2,887 hydromorphone drug items submitted to federal, state, and local forensic laboratories in 2009, 2010, and 2011, respectively. During the first three months of 2012, 754 items identified as hydromorphone were submitted to forensic laboratories.

The 2010 National Survey on Drug Use and Health (NSDUH) reported that 1.1 million individuals aged 12 and older used Dilaudid® for nonmedical purposes in their lifetime.

Control Status:

Hydromorphone products are 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 Email ODE@usdoj.gov.