data Enforcement Adults

August 2025 DEA/DC/DOE

METHADONE

(Trade Names: Methadose[®], Dolophine[®]; Street Names: Fizzies, Amidone, Chocolate Chip Cookies)

Introduction:

Methadone is a pharmaceutical opioid that has been used for over forty years, primarily in detoxification or maintenance programs to treat opioid addiction. Methadone is currently available as an oral concentrate (10 mg/ml), oral solution (5 and 10 mg/5ml), tablet (5, 10, and 40 mg), injection (10 mg/ml), and powder (50, 100, and 500 mg/bottle for prescription compounding).

In November 2006, the Food and Drug Administration (FDA) issued a public health advisory stating that methadone use in pain control may result in life-threatening cardiac and respiratory changes and deaths. FDA further advised that methadone doses for pain relief should be carefully selected, slowly titrated, and carefully monitored by the prescribing physician. As of January 1, 2008, manufacturers of 40 mg methadone hydrochloride dispersible tablets have voluntarily agreed to restrict distribution of this formulation to only hospitals and facilities authorized for detoxification and maintenance treatment of opioid addiction. The 40 mg methadone product is not FDA-approved for use in the management of pain.

Licit Uses:

Methadone products, when used for the treatment of narcotic addiction in detoxification or maintenance programs, should be dispensed only by pharmacies approved by appropriate regulatory authorities. When these products are used as analgesics, they may be dispensed by any licensed pharmacy.

According to IQVIA National Prescription Audit™, total prescriptions for methadone dispensed in the United States peaked in 2010 at approximately 4.4 million and then decreased each year to approximately 1.4 million in 2022, 1.3 million in 2023, and 1.2 million in 2024.

Chemistry:

Methadone is a synthetic drug. It is chemically known as (*RS*)-6-(dimethylamino)-4,4-diphenylheptan-3-one. The CAS number for methadone is 76-99-3. The chemical structure of methadone is shown below:

Pharmacology:

Methadone is a *mu*-opioid receptor agonist that binds strongly to proteins in various tissues, including the brain. Methadone has abuse potential and may produce psychic and physiologic dependence and tolerance. Upon discontinuation of its administration, low concentrations of methadone are maintained in the body due to the slow release of methadone from tissue binding sites. Notable features of methadone include its efficacy by the oral route, its prolonged duration of action in suppressing opioid withdrawal symptoms in physically dependent individuals, and its tendency to produce persistent effects with repeated administration.

Pharmacological and toxic effects, abuse, and dependence liabilities of methadone are qualitatively similar to those of other schedule II opioid analgesics, such as morphine and oxycodone. Analgesic activity of racemic methadone is entirely due to its *I*-isomer, which is 8 to 50 times more potent than its *d*-isomer. The *d*-isomer lacks significant respiratory

depressant action and addiction liability but possesses antitussive activity. The analgesic effect of 8 to 10 mg of methadone is almost equivalent to that of 10 mg of morphine. With respect to total analgesic effects, methadone given orally is one-half as effective as its intramuscular administration. Pain relief from a dose of methadone lasts about 4 to 8 hours, but the drug may stay in the body for 8 to 59 hours.

Acute overdose of methadone, similar to morphine, can produce severe respiratory depression, somnolence, coma, skeletal muscle flaccidity, cool clammy skin, constricted pupils, reduction in blood pressure and heart rate, pulmonary edema, and death.

Pure opioid antagonists such as naloxone are specific antidotes against respiratory depression from methadone overdose.

Illicit Uses:

Methadone is abused for its euphoric effects, as a substitute for other opioids, and as self-medication for withdrawal from other opioids.

America's Poison Centers reported that in 2022, methadone was associated with 1,731 case mentions, 864 single exposures, and 7 deaths. In 2023, methadone was associated with 1,648 case mentions, 802 single exposures, and 3 deaths.

According to the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, Wide-ranging ONline Data for Epidemiologic Research (WONDER) database, methadone was involved in over 4,500 drug overdose deaths in the United States in 2010, over 3,300 in 2015, over 3,500 in 2020, and over 3,200 in 2024 (provisional data).

The National Survey on Drug Use and Health indicated that in 2024, 206,000 individuals (0.1% of the population) aged 12 years or older reported misusing methadone in the past year. In 2020, 229,000 (0.4% of the population) individuals aged 12 or older reported misuse in the previous year.

Illicit Distribution:

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 has received over 109,000 reports of methadone identifications over all time, including 8,472 in 2010, 4,731 in 2015, 1,483 in 2020, and 938 in 2024.

Control Status:

Methadone 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.