Drug Enforcement Administration
Diversion Control Division
Drug & Chemical Evaluation Section

July 2026
DEA/DC/DOE

BUPRENORPHINE

(Trade Names: Buprenex®, Suboxone®, Subutex®)

Introduction:

Buprenorphine was first discovered in 1966 by Reckitt & Colman as an analgesic alternative to morphine. In 1981, buprenorphine was approved for marketing in the United States as an injectable formulation (Buprenex® 0.3 mg/ml) for the treatment of moderate to severe pain and was subsequently placed in schedule V of the Controlled Substances Act (CSA). In October 2002, the Food and Drug Administration (FDA) approved two sublingual products for the treatment of opioid use disorder (OUD)—Suboxone® (buprenorphine and naloxone) and Subutex® (buprenorphine)—and buprenorphine-containing products were rescheduled from schedule V to schedule III of the CSA. Since 2003, the trafficking, diversion, misuse and abuse of buprenorphine have increased in the United States; these illicit practices also have occurred in other areas of the world.

Licit Uses:

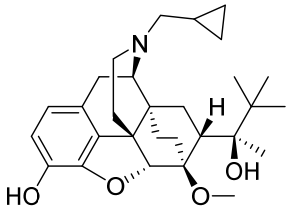
Buprenorphine is supplied for the treatment of pain as an injection, buccal film (Belbuca®), or transdermal patch (Butrans®). For OUD, buprenorphine is supplied as a sublingual tablet or an extended-release injectable solution (Brixadi®, Sublocade®). Buprenorphine with naloxone is supplied as a sublingual film (Suboxone®) or sublingual tablet (Zubsolv®).

According to IQVIA National Prescription Audit™, total prescriptions dispensed for buprenorphine-containing products in the United States was approximately 6.3 million in 2010, 12.4 million in 2015, 18.0 million in 2020, and 18.3 million in 2025.

Recent efforts have been made to expand patient access to medications for OUD. On December 29, 2022, with the signing of the Consolidated Appropriations Act of 2023, Congress eliminated the DATA-Waiver Program, allowing qualified practitioners to prescribe buprenorphine for OUD without a DATA-2000 waiver ("X-waiver"). Accordingly, there are no longer limitations, under federal law, on the number of patients with OUD that a practitioner may treat with buprenorphine, though practitioners are still required to comply with any applicable state limits regarding treatment of patients with OUD. Further, the Drug Enforcement Administration (DEA), jointly with the Department of Health and Human Services, issued a fourth extension of telemedicine flexibilities for the prescribing of controlled medications—including buprenorphine for OUD—through December 31, 2026.

Chemistry:

Buprenorphine is chemically known as (2*S*)-2-[(5*R*,6*R*,7*R*,14*S*)-17-cyclopropylmethyl-4,5-epoxy-6,14-ethano-3-hydroxy-6-methoxymorphinan-7-yl]-3,3-dimethylbutan-2-ol. The CAS number for buprenorphine is 52485-79-7. The chemical structure of buprenorphine is shown here:



Pharmacology:

Buprenorphine has a unique pharmacological profile and produces effects that are typical of both pure mu-opioid receptor agonists (e.g., morphine) and partial agonists (e.g., pentazocine), depending on the dose, pattern of use, and population taking the drug. Buprenorphine is a long-acting (24–72 hours) opioid that is about 20–30 times more potent than morphine as an analgesic. Like morphine, buprenorphine produces dose-related euphoria, drug-liking, pupillary constriction, and sedation. Chronic buprenorphine administration produces opioid-like physical dependence.

Buprenorphine blocks or diminishes the effects of concurrently administered full opioid agonists due to its mu-opioid receptor partial agonist activity. Buprenorphine produces less respiratory depression at high doses compared to other narcotic drugs; however, severe respiratory depression can still occur, especially when buprenorphine is combined with other central nervous system depressants like benzodiazepines.

Illicit Uses and User Population:

Like other opioids, buprenorphine can produce euphoria. Data from the United States and other countries indicate that buprenorphine has been misused through various routes of administration (e.g., sublingual, intranasal, injection) as both a heroin substitute and a primary drug of abuse.

America's Poison Centers reported that in 2022, buprenorphine was associated with 4,040 case mentions, 2,368 single exposures, and 1 death. In 2023, buprenorphine was associated with 3,842 case mentions, 2,163 single exposures, and 1 death.

Illicit Distribution:

DEA's National Forensic Laboratory Information System (NFLIS) Drug database is a system that 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 258,000 reports of buprenorphine since 1998, including 21,321 in 2019; 17,615 in 2020; 15,537 in 2021; 13,616 in 2022; 11,764 in 2023; 11,427 in 2024; and 11,493 in 2025.

Control Status:

Buprenorphine and all products containing buprenorphine are controlled in schedule III of the CSA.

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.