

Buprenorphine

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Buprenorphine is a medication approved by the Food and Drug Administration (FDA) to treat Opioid Use Disorder (OUD).

As the opioid crisis continues to be a pressing issue in the United States, SAMHSA and the FDA emphasize that healthcare practitioners must work collaboratively with patients, meeting them where they are, to create supportive and tailored treatment plans. Read the <u>Dear Colleague Letter:</u> <u>Medication First Model (PDF | 188 KB)</u>.

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What is Buprenorphine?

Buprenorphine is the first medication to treat opioid use disorder (OUD) that can be prescribed or dispensed in physician offices, significantly increasing access to treatment. As with all medications used in treatment, buprenorphine should be prescribed as part of a comprehensive treatment plan that includes counseling and other services to provide patients with a whole-person approach.

Buprenorphine offers several benefits to those with OUD and to others for whom treatment in an Opioid Treatment Clinic is not appropriate or is less convenient.

The following buprenorphine products are FDA approved for the treatment of OUD:

- Generic Buprenorphine/naloxone sublingual tablets
- Buprenorphine sublingual tablets (Subutex)

- Buprenorphine/naloxone sublingual films (Suboxone)
- Buprenorphine/naloxone) sublingual tablets (Zubsolv)
- Buprenorphine/naloxone buccal film (Bunavail)
- Buprenorphine implants (Probuphine)
- Buprenorphine extended-release injection (Sublocade)

Refer to the individual product websites for a complete listing of drug interactions, warnings, and precautions.

In addition, buprenorphine is also administered at <u>SAMHSA-certified opioid</u> <u>treatment programs</u> (OTPs). Find a <u>SAMHSA-certified OTP</u> in your local area.

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Buprenorphine Contacts

For information on buprenorphine and use of medications in office-based practices, contact the SAMHSA Center for Substance Abuse Treatment (CSAT) at <u>866-BUP-CSAT</u> (866-287-2728) or <u>providersupport@samhsa.hhs.gov</u>.

For clinical questions or mentoring, contact <u>pcssnow.org</u> 🛃.

Opioid Treatment Program Contacts

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For information about other medications for OUD treatment or the certification of opioid treatment programs (OTPs), contact the SAMHSA Division of Pharmacologic Therapies at <u>240-276-2700</u> or <u>DPT@SAMHSA.HHS.Gov</u>.

For assistance with the Opioid Treatment Program Extranet, contact the OTP helpdesk at <u>1-866-348-5741</u> or <u>OTP-Help@jbsinternational.com</u>.

Buprenorphine Guides

SAMHSA has developed a <u>Buprenorphine Quick Start Guide (PDF | 1.4 MB)</u> and <u>pocket guide (PDF | 200 KB)</u> for all practitioners seeking to prescribe buprenorphine.

How Buprenorphine Works

Buprenorphine is an opioid partial agonist. It produces effects such as euphoria or respiratory depression at low to moderate doses. With buprenorphine, however, these effects are weaker than full opioid agonists such as <u>methadone</u> and heroin.

When taken as prescribed, buprenorphine is safe and effective. Buprenorphine has unique pharmacological properties that help:

- Diminish the effects of physical dependency to opioids, such as withdrawal symptoms and cravings
- Increase safety in cases of overdose
- Lower the potential for misuse

Buprenorphine for Opioid Use Disorder

- To begin treatment, an OUD patient must abstain from using opioids for at least 12 to 24 hours and be in the early stages of opioid withdrawal. Patents with opioids in their bloodstream or who are not in the early stages of withdrawal, may experience acute withdrawal.
- After a patient has discontinued or greatly reduced their opioid use, no longer has cravings, and is experiencing few, if any, side effects, if needed, the dose of buprenorphine may be adjusted. Due to the long-acting agent of buprenorphine, once patients are stabilized, it may be possible to switch from every day to alternate-day dosing.
- The length of time a patient receives buprenorphine is tailored to meet the needs of each patient, and in some cases, treatment can be indefinite. To prevent possible relapse, individuals can engage in on-going treatment—with or without MOUD.

Common and Serious Side Effects of Buprenorphine



Patients who are considering buprenorphine for treatment, should be sure they fully understand the medication and its side effects before they take the medication. Their health care practitioner or pharmacist can provide this information. Patients should tell their health care

practitioner about any side effects that are bothersome, or do not go away.

Patients and practitioners are encouraged to report all side effects online to MEDWatch, FDA's medical product safety reporting program for health care professionals, patients, and consumers or by calling <u>1-800-FDA-1088</u>.

Common side effects of buprenorphine include:

- st. • Constipation, headache, nausea, and vomiting
- Dizziness •
- Drowsiness and fatigue
- Sweating
- Dry mouth
- Tooth decay
- Muscle aches and cramp
- Inability to sleep
- Fever
- Blurred vision or dilated pupils
- Tremors
- Palpitations
- Disturbance in attention

Serious side effects of buprenorphine include:

- Respiratory distress
- Overdose
- Adrenal insufficiency

- Dependence
- Withdrawal
- Itching, pain, swelling, and nerve damage (implant)
- Pain at injection site (injection)
- Neonatal abstinence syndrome (in newborns)

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Need Help?

 If you, or someone you know, need help to stop using substances – whether the problem is methamphetamine, alcohol or another drug – call <u>SAMHSA's National Helpline</u> at <u>1-800-662-HELP</u> (4357) or TTY: <u>1-800-487-4889</u>

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 <u>FindTreatment.gov</u> – this locator provides information on statelicensed providers who specialize in treating substance use disorders and mental illness.

Safety Precautions

People should use the following precautions when taking buprenorphine:

- Do not take other medications without first consulting your doctor.
- Do not use illegal drugs, drink alcohol, or take sedatives, tranquilizers, or other drugs that slow breathing. Mixing large amounts of other medications with buprenorphine can lead to overdose or death.
- Ensure that a physician monitors any liver-related health issues that you may have.
- Tell your doctor if you are pregnant or plan to become pregnant.
- Prevent children and pets from accidental Ingestion by storing it out of reach. For more information, visit CDC's <u>Up and Away</u> ² educational campaign.

- Dispose of unused methadone safely. Talk to your MOUD practitioner for guidance, or for more information on the safe disposal of unused medications, visit <u>FDA's disposal of unused medicines</u> or <u>DEA's drug disposal</u> webpages
- Do not shared your buprenorphine with anyone even if they have similar symptoms or suffer from the same condition.

Buprenorphine Misuse Potential

Because of buprenorphine's opioid effects, it can be misused, particularly by people who do not have an opioid dependency. <u>Naloxone</u> is added to buprenorphine to

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Tip 63: Medications for Opioid Use Disorder (2021)

This <u>Treatment Improvement Protocol</u> reviews the use of the three FDAapproved medications used to treat OUD.



SUBLINGUAL AND TRANSMUCOSAL BUPRENORPHINE FOR OPIOID USE DISORDER: REVIEW AND UPDATE

Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder (2016)

This advisory summarizes data on the use of sublingual and transmucosal

Treating Pregnant or Breastfeeding Women

102: Buprenorphine may be prescribed to women who are pregnant and have an QUE Buprenorphine and methadone are considered the treatments of choice for OUD in pregnant and breastfeeding women.

For more information about the use of medications during pregnancy refer to the Resources and Publications section below.

- <u>Advisory: Evidence-Based, Whole Person Care of Pregnant People Who Have</u> **Opioid Use Disorder - 2023**
- <u>A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use</u> Disorders - 2016
- <u>Are You Taking Medicine for Opioid Use Disorder and Are Pregnant or Thinking</u> about Having a Baby? - 2019
- <u>Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use</u> Disorder and Their Infants - 2018
- Good Care for You and Your Baby While Receiving Opioid Use Disorder Treatment - 2018
- Healthy Pregnancy Healthy Baby Fact Sheets 2018
- **Opioid Use Disorder and Pregnancy 2018**
- Treating Babies Who Were Exposed to Opioids Before Birth 2018
- Treating Opioid Use Disorder During Pregnancy 2018



Buprenorphine Trainings

SAMHSA offers tools, training, and technical assistance.



Other Medications for Substance Use Disorders 31/1202

Learn about other medication options.



Naltrexone

Naltrexone is a medication used to treat alcohol use disorder (AUD) and opioid use disorder (OUD).



Naloxone

Naloxone is an opioid antagonist medication that is used to reverse an opioid overdose.

Resources and Publications

- The Facts about Buprenorphine for Treatment of Opioid Addiction 2015 also available in Cambodian/Khmer, Chinese, Korean, Russian, Spanish, and Vietnamese
- Transitioning from Methadone to Buprenorphine

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