

**What Is SUBOXONE?**

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SUBOXONE is the **first opioid medication approved** under the Federal Drug Addiction Treatment Act (DATA) of 2000 **for the treatment of opioid dependence** during inpatient detoxification and outpatient at **an office-based setting**. SUBOXONE also can be dispensed for take-home use, just as any other medicine for other medical conditions.

**The primary active ingredient in SUBOXONE is buprenorphine.** Because buprenorphine is a partial opioid agonist, its opioid effects are limited compared with those produced by full opioid agonists, such as oxycodone or heroin.

**SUBOXONE also contains naloxone**, an opioid antagonist. The naloxone in SUBOXONE is there to discourage people from dissolving the tablet and injecting it. When SUBOXONE is placed under the tongue, as directed, very little naloxone reaches the bloodstream, so what the patient feels are the effects of the buprenorphine. However, if naloxone is injected, it can cause a person dependent on a full opioid agonist to quickly go into withdrawal.

**SUBOXONE at the appropriate dose may be used to reduce illicit opioid use and help patients stay in treatment** by suppressing symptoms of opioid withdrawal and decreasing cravings for opioids

**SUBOXONE Treatment**

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SUBOXONE treatment occurs in four stages: Induction, Stabilization, Maintenance, and Medically Supervised Withdrawal.

**Induction**

The goal of induction is to safely **suppress opioid withdrawal as rapidly as possible** with adequate doses of SUBOXONE. Patients may experience mild-to-moderate opioid withdrawal symptoms. The induction phase usually averages 2 to 5 days.

Although the details will vary between practices, the first induction visit generally proceeds as follows:

1. Patient's withdrawal symptoms are assessed and document.
2. The first dose of SUBOXONE is administered.
3. One to two hours later, the patient's withdrawal symptoms are reassessed, and a second dose of SUBOXONE is administered if needed.
4. Some physicians prefer to prescribe enough SUBOXONE so that patients can take additional doses at home as needed.

Induction is completed when the patient:

- Experiences no withdrawal symptoms
- Experiences minimal to no side effects
- Has no uncontrollable cravings for opioids
- Is not using additional opioids

**Stabilization**

During stabilization, the patient's SUBOXONE **dose is "fine-tuned."** The objective is to find the minimum dose necessary to hold the patient in treatment, suppress opioid withdrawal effects, and suppress other opioid use (this dose can be anywhere from 4 to 24 mg per day, depending on the individual).

Doses are progressively adjusted in increments or decrements of 2 to 4 mg. After each dose adjustment, 3 to 7 days should be allowed for steady-state blood levels to be achieved, before evaluating the need for further dose changes.

### ***Maintenance***

The goals of the maintenance phase are to **prevent** opioid withdrawal symptoms and to **suppress** opioid cravings

SUBOXONE therapy and psychosocial counseling continue. Treatment compliance and progress are regularly monitored, and may entail urine screening tests and other laboratory evaluations as appropriate.

As the patient moves further along in his or her treatment and his or her condition improves, the need for frequent monitoring generally abates. The duration of the maintenance phase depends on the individual needs of the patient and can range from weeks to years.

### ***Medically Supervised Withdrawal***

Medically supervised withdrawal from SUBOXONE should occur only when the patient and physician agree that to do so would be beneficial. The patient's SUBOXONE dose should be slowly tapered at a rate that both physician and patient consider acceptable. It is not uncommon for patients to want to taper more, rather than less, quickly, so helping patients set realistic goals is important from the outset.

Patients should be prepared for the possibility of mild, transitory withdrawal symptoms, which may include reduced energy, reduced appetite, irritability, or insomnia. It is also important for patients to understand that they can halt the medical withdrawal at any time and return to a higher dose.

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## **Who Can Prescribe SUBOXONE?**

**Doctors, including psychiatrists, need to be certified to prescribe SUBOXONE.** Doctors who are already specialists in addiction medicine or who complete specific training can become certified to treat opioid dependence with SUBOXONE in their offices.

A listing of certified physicians can be found on the Internet through the **Here to Help Program** ([www.heretohelpprogram.com](http://www.heretohelpprogram.com)).

Physicians interested in becoming certified to prescribe SUBOXONE can contact one of the following organizations for appropriate training courses.

#### **American Academy of Addiction Psychiatry (AAAP)**

Phone: (401) 524-3076

Contact: [www.aaap.org/contact.htm](http://www.aaap.org/contact.htm)

Website: [www.aaap.org](http://www.aaap.org)

#### **American Osteopathic Academy of Addiction Medicine (AOAAM)**

Phone: (800) 621-1773

Website: [www.aoaam.org](http://www.aoaam.org)

#### **American Psychiatric Association (APA)**

Phone: (703) 907-7300

E-mail: [apa@psych.org](mailto:apa@psych.org)

Website: [www.psych.org](http://www.psych.org)

#### **American Society of Addiction Medicine (ASAM)**

Phone: (301) 656-3920

E-mail: [email@asam.org](mailto:email@asam.org)

Website: [www.asam.org](http://www.asam.org)

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## **Benefit Coverage for SUBOXONE**

Currently most health plans are covering SUBOXONE under the pharmacy benefit, however, pre-authorization is required.

Health plans have not clearly defined coverage of SUBOXONE Induction and/or ongoing outpatient SUBOXONE Maintenance. If a referral for SUBOXONE treatment is indicated, the patient and/or provider must contact the health plan directly to determine coverage available prior to starting treatment.

## SUBOXONE Resources

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[www.SUBOXONE.com](http://www.SUBOXONE.com): This is the primary website for SUBOXONE information.

[www.heretohelpprogram.com](http://www.heretohelpprogram.com): This website provides self-help and coaching resources for patients currently taking SUBOXONE. Therapists and Physicians can also login and register.

[www.naabt.org](http://www.naabt.org): This is the website for National Alliance of Advocates for Buprenorphine Treatment. Referral resources are available for patients and providers.

## Safety Information About SUBOXONE

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- **SUBOXONE combined with medications/drugs:** It can be dangerous to mix SUBOXONE with drugs like benzodiazepines, alcohol, sleeping pills and other tranquilizers, certain antidepressants, or other opioid medications, especially when not under the care of a doctor or in doses different from those prescribed. Mixing these drugs can lead to drowsiness, sedation, unconsciousness, and death, especially if injected.
- **Potential for dependence:** SUBOXONE and SUBUTEX® CIII (buprenorphine HCl sublingual tablets) have potential for abuse and produce dependence of the opioid type with a milder withdrawal syndrome than that of full agonists.
- **Pregnancy:** There are no adequate and well-controlled studies of SUBOXONE (a Category C medication) in pregnancy. SUBOXONE should not be taken during pregnancy unless a doctor determines that the potential benefit justifies the potential risk to unborn child.
- **Breast-feeding:** Buprenorphine will pass through a mother's milk and may harm the baby, so SUBOXONE is not recommended for women who are breast-feeding.
- **Driving and operating machinery:** SUBOXONE can cause drowsiness and slow reaction times. This may occur more often in the first few weeks of treatment, when the dose is being changed, but can also occur if combined with alcohol or other sedative drugs. Caution should be exercised when driving cars or operating machinery.
- **Commonly reported side effects:** Side effects of SUBOXONE are similar to those of other opioids. The most commonly reported adverse events with SUBOXONE include: headache, withdrawal syndrome, pain, insomnia, nausea, and constipation. Please see full Product Information for a complete list.
- **SUBOXONE use in children:** SUBOXONE can be used in people ages 16 and older. It hasn't been approved for use in children younger than 16.
- **Appropriate use of SUBOXONE:** Do not use SUBOXONE or SUBUTEX for conditions for which they were not prescribed. Patients with a clinical need for analgesia should not be transferred to a SUBOXONE regimen. SUBOXONE is not indicated for pain management.