

Suboxone®

(buprenorphine)



12 Questions & Answers

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Buprenorphine (Suboxone)

Buprenorphine, when appropriately prescribed and taken, is an effective, safe medication approved by the FDA for use in the treatment of opioid addiction. Buprenorphine relieves withdrawal, reduces craving and blocks the effects of heroin in ways similar to methadone.

Unlike methadone, buprenorphine may be prescribed for treatment of opioid addiction by any doctor who has received training and a waiver from the DEA. This is its principal advantage over methadone for most doctors and patients. Misuse of buprenorphine is less likely than methadone to result in death.

Prescribed in the U.S. as Suboxone or Subutex, buprenorphine is usually taken daily as tablets to be dissolved under the tongue. There is little effect from the drug if it is swallowed. Suboxone contains not just buprenorphine but also naloxone, an opioid antagonist that may precipitate withdrawal symptoms if injected.

For people dependent on any opioid, taking the first dose of buprenorphine when not in withdrawal can result in acute withdrawal symptoms. Buprenorphine, like methadone, can be used as a short- or long-term detoxification medication or indefinitely as a maintenance medication. The risks of relapse following detoxification appear to be similar whether methadone or buprenorphine (or any drug-free treatment modality) is used.

A directory of physicians approved to prescribe buprenorphine can be found at:

http://buprenorphine.samhsa.gov/bwns_locator/



12 Questions and Answers:

- 1. What is Suboxone?**

Suboxone is a medication approved for the treatment of opiate dependence. This medicine contains the active ingredient, buprenorphine hydrochloride, which works to reduce the symptoms of opiate dependence.
- 2. Why did the FDA approve Suboxone and Subutex?**

Subutex contains only buprenorphine hydrochloride. The second medication, Suboxone contains an additional ingredient called naloxone to guard against misuse.
- 3. Will most prescriptions be for the Suboxone formulation?**

Yes, Suboxone is the formulation used in the majority of patients. It comes in sublingual (placed under the tongue to dissolve) tablets and film.
- 4. How are Suboxone different from the current treatment options for opiate dependence such as methadone?**

Currently opiate dependence treatments like methadone can be dispensed only in a limited number of clinics that specialize in addiction treatment. There are not enough addiction treatment centers to help all patients seeking treatment. Suboxone is the first narcotic drug available under the Drug Abuse Treatment Act (DATA) of 2000 for the treatment of opiate dependence that can be prescribed in a doctor's office. This change will provide more patients the opportunity to access treatment.

5. **What are some possible side effects of Suboxone?**

(This is NOT a complete list of side effects reported with Suboxone. Refer to the package insert for a more complete list of side effects.) The most common reported side effect of Suboxone include:

- * Cold or flu-like symptoms
- * Headaches
- * Sweating
- * Sleeping difficulties
- * Nausea
- * Mood swings.

Like other opioids Suboxone have been associated with respiratory depression (difficulty breathing) especially when combined with other depressants.

6. **Are patients able to take home supplies of these medicines?**

Yes. Suboxone are less tightly controlled than methadone because they have a lower potential for abuse and are less dangerous in an overdose. As patients progress on therapy, their doctor may write a prescription for a take-home supply of the medication.

7. **How will FDA know if Suboxone is being misused, and what can be done if it is?**

FDA has worked with the manufacturer, Reckitt-Benckiser, and other agencies to develop an in depth risk-management plan. FDA will receive quarterly reports from the comprehensive surveillance program. This should permit early detection of any problems. Regulations can be enacted for tighter control of Suboxone treatment if it is clear that it is being widely diverted and misused.

8. **What are the key components of the risk-management plan?**

The main components of the risk-management plan are preventive measures and surveillance. Preventive Measures include:

- * Education
- * Tailored distribution
- * Schedule III control under the Controlled Substances Act (CSA)
- * Child resistant packaging
- * Supervised dose induction

9. **Who can prescribe Suboxone?**

Only qualified doctors with the necessary DEA (Drug Enforcement Agency) identification number are able to start in-office treatment and provide prescriptions for ongoing medication. CSAT (Center for Substance Abuse Treatment) will maintain a database to help patients locate qualified doctors.

10. **How will Suboxone be supplied?**

Suboxone comes in 2/0.5 mg and 8/2 mg strengths buprenorphine/naloxone sublingual tablets.

11. **Where can patients get Suboxone?**

These medications will be available in most commercial pharmacies. Qualified doctors with the necessary DEA identification numbers will be encouraged to help patients locate pharmacies that can fill prescriptions for Suboxone.

12. **Where can I go for more information?**

- * Go to:

<http://www.suboxone.com/>

The Stages of Treatment:

The steps in medically-assisted treatment with buprenorphine for opioid dependence are:

1. **Induction**—Your treatment with a buprenorphine-only medication begins. Induction is generally considered the first 2-3 days of your treatment.
2. **Maintenance**—During this phase, your doctor will prescribe Suboxone SL tablets or Film. The doctor sees you regularly to monitor progress, address any issues, and help you begin ongoing counseling.
3. **Medical Taper**—If you and your healthcare team determine the time is right, your doctor slowly tapers down your dose.

More resources on buprenorphine (Suboxone):

www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm

* Contact the CSAT Buprenorphine Information Center at 866-BUP-CSAT

or via email at

info@buprenorphine.samhsa.gov or
<http://buprenorphine.samhsa.gov/>