

**Suboxone® C-III**  
**(buprenorphine HCl/naloxone HCl dihydrate)**  
**Sublingual Tablets**

## **Questions and Answers**

*Millions of Americans who are properly treated for pain become addicted to prescription painkillers, destroying families and ruining lives. Dependence on prescription painkillers, as well as on other opioids such as heroin, is a chronic brain disease that involves a physical, psychological, and behavioral need that is unrelated to medical necessity for analgesia. Opioid dependence can now be conveniently treated in the privacy of a doctor's office and through prescriptions with Suboxone (buprenorphine/naloxone); best results should be obtained when treatment with Suboxone is combined with appropriate psychosocial counseling and other support. Suboxone is a medicine that helps patients gain control over their dependence, so that they can work to rebuild their lives. Because Suboxone is a partial opioid agonist, patients can develop opioid dependence on Suboxone.*

- **Why use Suboxone (buprenorphine/naloxone) for the treatment of opioid dependence?**  
Suboxone is the first controlled narcotic approved by the FDA for treatment of opioid dependence in an office-based setting, under special legislation. The Drug Addiction Treatment Act of 2000 (DATA 2000) now allows patients to be treated for the chronic brain disease of opioid dependence in the privacy of their physicians' offices, with follow-on maintenance prescriptions, just as they would for other chronic conditions such as diabetes, hypertension, or depression. Office-based treatment with Suboxone, as opposed to treatment with methadone dispensed through daily visits at a drug treatment center, marked a revolutionary change in the way opioid dependence can be treated. As doctors across the United States become certified to treat patients dependent on prescription painkillers and other opioids, patients' access to treatment will be significantly expanded to include small towns and rural areas as well as large metropolitan centers.

- **How are opioid dependent patients treated with Suboxone?**

Opioid dependent patients can be treated with Suboxone in the privacy of a certified doctor's office. After initial "induction" to get treatment started, at the doctor's discretion patients can be given prescriptions for maintenance therapy of this chronic brain disease. Physicians prescribe Suboxone based on their assessment of the patient's particular situation. Suboxone is taken sublingually, meaning the medication tablet is placed under the tongue where it will dissolve.

- **How does Suboxone help treat opioid dependence – what is its mechanism of action?**

Suboxone is made of two components, buprenorphine and naloxone. Buprenorphine is a clinically active partial agonist that binds to the same opioid receptors in the brain that otherwise would bind to molecules of opioid painkillers or heroin. Naloxone is clinically inactive when taken sublingually as directed. Buprenorphine binds tightly to the receptor and is not easily displaced by other opioids (like a parking space in the brain that has been taken). But because buprenorphine is only a partial opioid agonist (rather than a full agonist, like methadone, heroin, or opioid painkillers), it does not activate the opioid receptors to the same degree as full agonists do.

- **What are the clinical effects of Suboxone and how do these benefit patients?**

- Because it is a partial agonist, buprenorphine by itself lowers respiration to a lesser extent than do full opioid agonists. However, when buprenorphine is used intravenously or in combination with other Central Nervous System depressants, serious adverse events and even death have been reported.
- Because buprenorphine binds tightly to opioid receptors, it is difficult to displace by other opioids. This means that patients derive minimal additional reinforcement if they attempt to use other opioids, such as prescription painkillers or heroin, while being treated with appropriate doses of Suboxone.
- Suboxone works by effectively suppressing withdrawal symptoms and by reducing or eliminating drug cravings to assist patients in reducing illicit opioid use and maintaining their opioid dependence treatment.
- Because buprenorphine stays in the body a long time and comes off opioid receptors slowly (called slow dissociation), it is thought to be easier for patients to withdraw from buprenorphine than is the case with full opioid agonists. Similarly, Suboxone's action as a partial agonist means that patients are likely to have milder symptoms of physiological withdrawal following chronic dosing compared to withdrawal from full opioid agonists.

- **Do patients treated with Suboxone also need to seek psychosocial counseling?**

Many patients and their doctors find that treatment for opioid dependence works best when medical treatment with Suboxone is combined with counseling. Patients should always consult with their doctor about the most appropriate course of therapy for their individual needs. To view real patients' testimonials about their own experiences with treatment for opioid dependence using Suboxone, visit [www.turntohelp.com](http://www.turntohelp.com) or [www.suboxone.com](http://www.suboxone.com).

- Can anyone who is dependent on opioids be treated with Suboxone?**  
 Although Suboxone is an important addition to the medical armamentarium to treat opioid dependence, given individual circumstances, Suboxone may not be suitable for every dependent patient. Patients should consult with their physicians as to the best treatment options for them.
- Is it safe to treat children or adolescents with Suboxone?**  
 Suboxone is indicated to treat opioid dependence in persons 16 years of age and older. To date, Suboxone has not been studied in children.
- Is it safe for pregnant women to be treated with Suboxone for opioid dependence?**  
 Suboxone is not approved by the FDA for use during pregnancy. Women who are being treated with Suboxone for opioid dependence should consult with their physician immediately if they become pregnant or plan to become pregnant.
- What is “DATA”?**  
 In 2000, Congress passed the Drug Addiction Treatment Act (DATA 2000) allowing certified physicians to prescribe Schedule III-V drugs to treat opioid dependence in an office-based setting. Buprenorphine is uniquely qualified under “office-based opioid treatment,” and under DATA is the only controlled medication with FDA approval to treat opioid dependence in a doctor’s office and with maintenance prescriptions.
- Are there any special requirements for physicians to prescribe Suboxone?**  
 To prescribe Suboxone, most doctors must take 8 hours of authorized training on the treatment or management of opioid-dependent patients, notify the government of their intent to treat opioid-dependent patients, and obtain a DEA waiver to become certified to prescribe Suboxone. Doctors who hold board certifications in addiction medicine through the American Board of Medical Specialties, the American Society of Addiction Medicine, or the American Osteopathic Association are not required to take the 8-hour course. Physicians who are interested in prescribing Suboxone can visit [www.docoptin.com](http://www.docoptin.com) or [www.buprenorphine.samhsa.gov](http://www.buprenorphine.samhsa.gov).
- What is the 100-patient limit?**  
 In December 2006 under DATA 2000, the Controlled Substances Act was modified to raise the patient limit from 30 patients per physician to 100 for those who have been certified for one year and who re-notify the Center for Substance Abuse Treatment (CSAT) of their intent to treat 100 patients in an office-based setting at any one time.
- How many U.S. physicians currently are certified to prescribe Suboxone for treatment of opioid dependence?**  
 As of mid-2008, approximately 14,000 doctors are certified to write prescriptions for Suboxone in the United States (source: IMS Health).

- How many patients use Suboxone to treat opioid dependence?**  
As of mid-2008, over 640,000 patients have been treated with Suboxone in the United States since product launch in early 2003 (source: internal estimate based on IMS Health).
- How is Suboxone different from Subutex®?**  
In the U.S., the primary formulation of buprenorphine is Suboxone, a combination of buprenorphine and naloxone. Naloxone is an opioid antagonist that causes severe withdrawal if Suboxone is injected intravenously by a person dependent on a full opioid agonist. There is also a buprenorphine formulation called Subutex, which does not contain naloxone; Subutex is primarily used only for initial “induction” to buprenorphine to get treatment started under a doctor’s direct supervision and for patients that are allergic to naloxone. Subutex is not routinely prescribed for at-home maintenance therapy in the U.S.
- What are the possible side effects from being treated with Suboxone?**  
Clinical studies have shown that the most common adverse events associated with buprenorphine were headache, withdrawal syndrome, pain, nausea and sweating; for a fuller listing, see “Important Safety Information” below. As with other opioids there is also the risk of fatal respiratory depression, though because buprenorphine is a partial opioid agonist, the risk with buprenorphine is less than with full opioid agonists, such as prescription painkillers, heroin, and methadone.
- How can people obtain more information about opioid dependence and Suboxone?**  
There are many resources available for people who want to learn about opioid dependence and its treatment options. Please see:

  - [www.turntohelp.com](http://www.turntohelp.com)
  - [www.suboxone.com](http://www.suboxone.com)
  - [www.buprenorphine.samhsa.gov](http://www.buprenorphine.samhsa.gov)

### **About Reckitt Benckiser Pharmaceuticals Inc.**

Reckitt Benckiser Pharmaceuticals Inc. is a specialty pharmaceutical company that markets Suboxone® (buprenorphine HCl/naloxone HCl dihydrate [2 mg/0.5 mg and 8 mg/2 mg]) C-III Sublingual Tablets and Subutex® (buprenorphine HCl [2 mg and 8 mg]) C-III Sublingual Tablets, formulations of buprenorphine used to treat opioid dependence in a medical office-based setting. Suboxone and Subutex, manufactured by Reckitt Benckiser Healthcare Ltd., are the only controlled medications under the Drug Addiction Treatment Act of 2000 approved by the FDA for office-based treatment of opioid dependence. Reckitt Benckiser Pharmaceuticals Inc. is committed to expanding access to medical therapies for patients suffering from the chronic, relapsing brain disease of opioid dependence. For more information, visit [suboxone.com](http://suboxone.com) or [turntohelp.com](http://turntohelp.com). Reckitt Benckiser Pharmaceuticals Inc. is a wholly owned subsidiary of Reckitt Benckiser PLC, a publicly traded UK firm.

### **Important Safety Information**

SUBOXONE® (buprenorphine HCl/naloxone HCl dihydrate CIII sublingual tablets) is indicated for the treatment of opioid dependence.

Buprenorphine, particularly when taken by the intravenous route, in combination with benzodiazepines or other CNS depressants (including alcohol) has been associated with significant respiratory depression and death.

SUBOXONE has potential for abuse and produces dependence of the opioid type, with a milder withdrawal syndrome than full agonists.

Cytolytic hepatitis and hepatitis with jaundice have been observed in the addicted population receiving buprenorphine.

There are no adequate and well-controlled studies of SUBOXONE (a Category C medication) in pregnancy.

Caution should be exercised when driving cars or operating machinery.

Always store buprenorphine-containing medications safely and out of the reach and sight of children. Destroy any unused medication appropriately.

The most commonly reported adverse events with SUBOXONE include: headache (36%, placebo 22%), withdrawal syndrome (25%, placebo 37%), pain (22%, placebo 19%), insomnia (14%, placebo 16%), nausea (15%, placebo 11%), and constipation (12%, placebo 3%). Please see full Prescribing Information for a complete list.

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