Attention Healthcare Provider

This patient is taking a combination drug of buprenorphine, a partial opiate agonist, and naloxone, an opioid antagonist (naloxone is only clinically active when abused parenterally). Patients taking buprenorphine may have a diminished response to opiate medications (including those for the management of cough or pain). Opiate-containing preparations should be avoided when non-opiate therapy is available as an alternative.

In an emergency situation requiring pain relief in patients taking buprenorphine, a suggested plan of management is regional anesthesia, conscious sedation with a benzodiazepine, use of non-opioid analgesics or general anesthesia.

In a situation requiring opiate analgesia, the dose of opiate required may be greater than usual. A rapidly acting opiate analgesic, which minimizes the duration of respiratory depression, should be used. The dose of opioid medication should be titrated against the patient's analgesic and physiological response, with close monitoring by trained staff.

Overdose with buprenorphine alone is uncommon. In a situation that a patient taking buprenorphine has overdosed and is unconscious, the primary management should be the re-establishment of adequate ventilation with mechanical assistance of respiration, if required. Overdose in combination with other CNS depressants should be considered because of the increased potential for life-threatening events. Naloxone may not be effective in reversing any respiratory depression produced by buprenorphine. High doses of naloxone hydrochloride, 10-35 mg/70 kg, may be of limited value in the management of buprenorphine overdose. Doxapram (a respiratory stimulant) has also been used.

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(buprenorphine HCl/naloxone HCl dihydrate) C-III sublingual tablets

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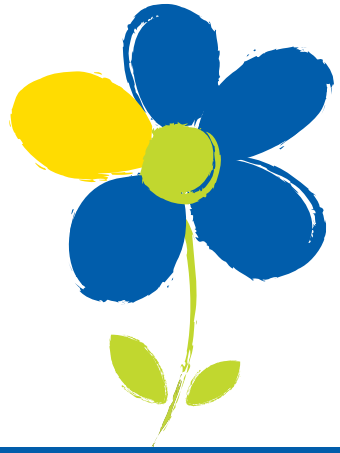
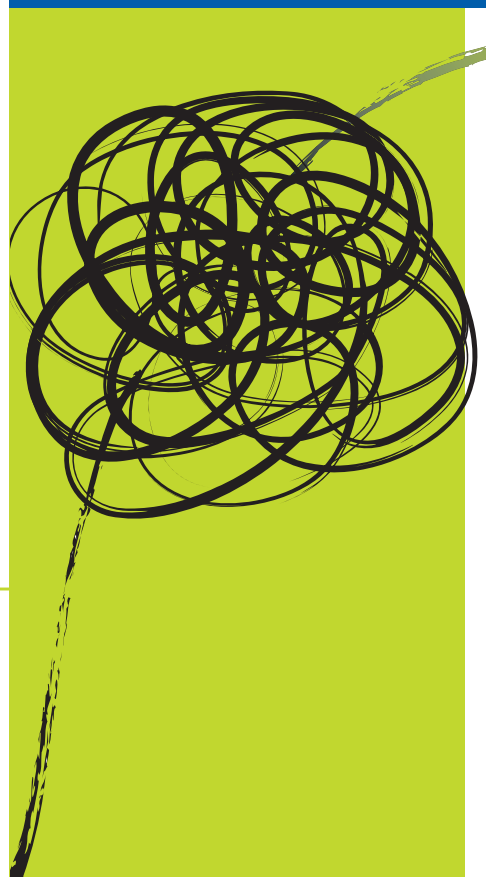
FACTS FOR PATIENTS



Embrace Treatment *Regain Control*



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Please see attached full Prescribing Information.

Introduction

Since 2000, when the Drug Addiction Treatment Act (DATA 2000) was passed by Congress, doctors have been able to treat ***opioid dependence*** *in an office setting as well as in a specially licensed clinic or hospital. SUBOXONE is the first opioid medication approved under DATA 2000 for the treatment of opioid dependence in an office-based setting. If you are experiencing opioid dependence, you and your doctor can decide what treatment is right for you based on your needs. Many people are able to take SUBOXONE at home, just like any other medicine for other medical conditions, after the doctor has determined the right dose. Daily visits for treatment are not necessary after your dose is established.*

Note: Words in **bold type** are explained in the glossary, which begins on page 26.

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Suboxone®
(buprenorphine HCl/naloxone HCl dihydrate) SL sublingual tablets

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Table of Contents

Please see attached full Prescribing Information.

Suboxone® (buprenorphine HCl/naloxone HCl dihydrate) sublingual tablets

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What Is an Opioid?

Opioids are drugs that are either derived from opiates (drugs created directly from opium, such as morphine or codeine) or are chemically related to opiates or opium. Examples of opioids include some prescription painkillers (such as oxycodone, hydrocodone, buprenorphine, methadone, and heroin).

What Is Opioid Dependence?

An individual is generally considered opioid-dependent when 2 things occur:

- Repeated opioid use is needed in order to feel good or avoid feeling bad, *and*
- The opioid use continues in spite of its negative effects. For example, people who are opioid-dependent will feel a need to keep using opioids even if it hurts their health, job, finances, or family

What Are Common Characteristics of Opioid Dependence?

- Opioid **tolerance** (the need to take more drug to get the same effect, or getting less effect from the same amount of the drug)
- Withdrawal symptoms occur when opioids are not used
  – Taking other drugs to help relieve the symptoms
- Taking larger amounts of opioids than planned and for longer periods of time
- Persistent desire or unsuccessful attempts to quit
- Spending a lot of time and effort to obtain, use, and recover from opioid use
- Giving up or reducing social or recreational activities; missing work
- Continued opioid use regardless of negative consequences

Patients displaying 3 or more of the above in a 12-month period are considered opioid-dependent.

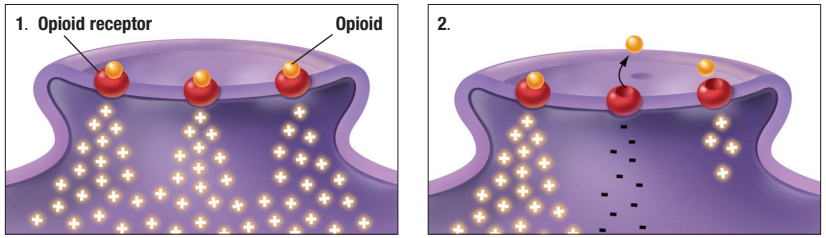
People with a clinical need for pain relief should not be transferred to SUBOXONE. SUBOXONE is not indicated for the treatment of pain.

Is Opioid Dependence a Medical Condition?

Opioids, such as some prescription pain medications or heroin, attach to **opioid receptors** in the brain, which stimulate the release of **dopamine** and produce pleasurable feelings. When the opioid eventually detaches from the receptors, people experience **withdrawal** and **cravings** and have a strong need to repeat the experience. Drug use often begins as a choice, but frequent use can cause the brain cells to change the way they work. The brain is "re-set" to think that the drug is necessary for survival. Researchers have discovered that many drugs, including opioids, cause long-term changes in the brain. These changes can cause people to have cravings years after they stop taking drugs.

Can Opioid Dependence Affect Behavior?

The need to satisfy cravings or avoid withdrawal can be so intense that people who want to stop taking opioids find this difficult to do. Or, they may find themselves doing things they wouldn't ordinarily do in order to obtain more of the drug they crave. For this reason, even though opioid dependence is a medical condition and not a moral failing, it can drive behavior.



1. Dopamine is released and produces pleasurable feelings (**+**). **2.** As the opioid leaves the receptors, pleasurable feelings subside and possible cravings and withdrawal symptoms (**-**) begin.

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How Common Is Opioid Dependence?

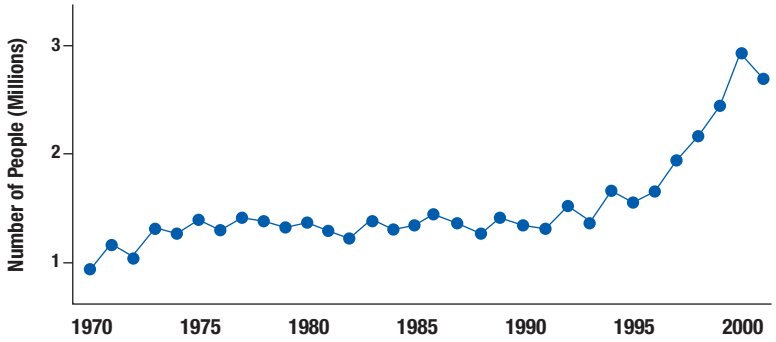
Opioid dependence is more common than you may think. You are not alone. No one group of people is immune to opioid dependence. Men and women of all ages, races, ethnic groups, and educational levels can become dependent on opioids.

How Common Is Misuse of Prescription Pain Medications?

According to the 2003 National Survey on Drug Use and Health (NSDUH):

- 4.7 million people ages 12 and older were misusing pain relievers in 2003
- By 2003, 31.2 million people ages 12 and older had used pain relievers nonmedically in their lifetime
- In 2001 alone, almost 2.5 million people used pain relievers nonmedically for the first time. This is a dramatic 335% increase from 573,000 new users in 1990

Misuse of Pain Relievers Increased Dramatically From 1970 to 2001*



*Taken from a NSDUH chart showing the number of people ages 12 and older who used pain relievers recreationally for the first time.

How Common Is Heroin Use?

In 2002, more than 400,000 people ages 12 and over reported using heroin in the previous year. An estimated 3.7 million people reported having used heroin at some time in their lives.

Recently, inexpensive, high-purity heroin has become more available. Rather than injecting, many new users are smoking or snorting heroin, with the misperception that these routes are less addictive. In addition, use among younger adults is growing in many suburban communities.

Why Are Some People More Likely to Become Dependent?

Substances such as opioids that produce **euphoria** are considered to have high reinforcement potential, which increases the likelihood that they will be taken repeatedly or abused, although a majority of people who take these powerfully reinforcing drugs do not become dependent on them. Although the specific causes vary from person to person, certain factors, such as the drug itself, genetics, and the individual's environment, are known to be important in the development of opioid dependence. Some people appear to be genetically predisposed to dependence, raising the possibility that susceptibility to the disease may be hereditary. Also, individual absorption levels of the drug into the blood can vary widely for different people, thus causing different effects. Lastly, substance abuse, which can lead to dependence, is often influenced by societal norms and peer pressure.

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Why Do Prescription Pain Medications Result in Dependence in Some People?

Even when used properly, medications prescribed for acute, chronic, or postoperative pain can cause symptoms of tolerance and withdrawal, which can stimulate you to want to take more, setting up the cycle of craving. Tolerance means that you need more of the drug to get the same pain relief. Just because you have developed tolerance for a drug does not mean that you are dependent on it or are abusing it. **Physical dependence** is typically associated with tolerance, and also with withdrawal, an adverse physiological effect that occurs when blood/tissue concentrations of a drug decline. Symptoms of withdrawal include extreme nausea, generalized pain, sweating, headache, irritability, and shaking. **Psychological dependence** involves continued drug use for reasons other than tolerance and withdrawal, such as to experience a drug's pleasurable effects. People with a clinical need for pain relief should not be transferred to SUBOXONE. SUBOXONE is not indicated for the treatment of pain.

What Is SUBOXONE?

SUBOXONE is the first opioid medication approved under DATA 2000 for the treatment of opioid dependence in a private office setting.

Buprenorphine is a **partial opioid agonist** that blocks other opioids from attaching to receptors in the brain. This treatment can help you stop misusing opioids. Treatment, including counseling, can help you rebuild your life.

What Is a Partial Opioid Agonist?

A partial agonist is an opioid that produces less effect than a full agonist when it binds to opioid receptors in the brain. The way different opioids work can be explained using a lock and key example. Receptors are like a lock to a door. Only the right key will fit the lock, and only opioid-like drugs fit opioid receptors.

A partial opioid agonist produces limited effects but doesn't allow other opioids to enter.

A full opioid agonist produces full opioid effects.

- With a **full opioid agonist** such as oxycodone, hydrocodone, morphine, methadone, or heroin, the key fits the lock, opens the door wide, and produces full opioid effects (the feeling of euphoria, or being high, as well as the side effects)
- With a partial opioid agonist such as buprenorphine, the key fits the lock but doesn't open the door all the way, so it produces less than full opioid agonist effects and, at the appropriate dose, blocks other opioids from opening the door fully
- An opioid **antagonist** such as naltrexone or naloxone fits in the lock but does not open the door at all and, at the appropriate dose, blocks other opioids from opening the door

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At appropriate doses SUBOXONE can:

- Help to suppress withdrawal from prescription pain medications, heroin, or similar full opioid agonists
- Help to decrease cravings for other opioids
- Reduce the effects of full opioid agonists

What Is Naloxone and Why Is It in SUBOXONE?

Naloxone is a medication that is used to reverse overdoses of opioids. It does this by knocking other opioids off the receptors, preventing negative effects such as respiratory depression (slowed breathing). Naloxone does not interfere with buprenorphine's effects when the SUBOXONE is taken under the tongue as prescribed.

When SUBOXONE is placed under the tongue as prescribed, very little naloxone is absorbed into the bloodstream. The patient should not feel the effects of naloxone. The naloxone in SUBOXONE is there to deter people from dissolving SUBOXONE and injecting it. When SUBOXONE is used incorrectly (by injection), its naloxone component can cause withdrawal symptoms to rapidly occur.

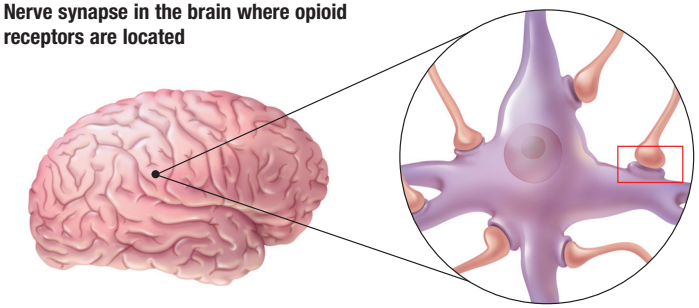
Subutex® Ⓒ (buprenorphine HCl sublingual tablets) contains only buprenorphine, without naloxone, and may be used to start people on treatment for opioid dependence.

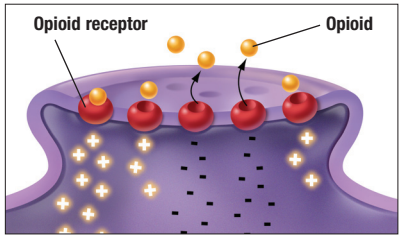
Please see attached full Prescribing Information.

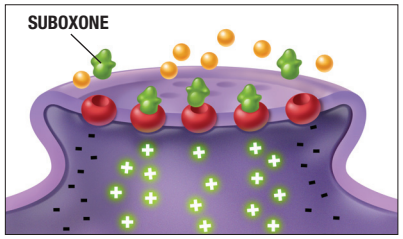
How Does SUBOXONE Work?

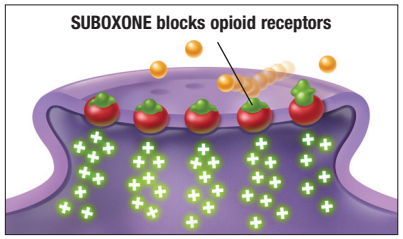
Buprenorphine, the active ingredient in SUBOXONE, works by strongly binding to opioid receptors.

Nerve synapse in the brain where opioid receptors are located









As SUBOXONE therapy begins:

1. A person is in a mild-to-moderate state of withdrawal (-) as the opioid of dependence begins to leave the receptors.

2. Buprenorphine attaches to receptors as the other opioid leaves the person's system. Withdrawal symptoms start to get better (+) because buprenorphine is filling up the receptors. In addition, buprenorphine reduces cravings.

3. Buprenorphine firmly attaches to the receptors and blocks other opioids from attaching. With adequate maintenance doses, buprenorphine fills most receptors. The buprenorphine has a long duration of action, so it doesn't wear off quickly.

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How Does SUBOXONE Benefit You?

SUBOXONE can decrease cravings and relieve withdrawal symptoms. This can help you remain in treatment and gain control over your dependence without the distraction of cravings and fear of withdrawal.

SUBOXONE offers a way to treat opioid dependence—in a doctor's office—with privacy, confidentiality, and safety. People treated with SUBOXONE generally don't need to be hospitalized, make daily visits to a clinic, or go away from home for residential treatment. As a result, treatment with SUBOXONE may allow more time for work, family, and other activities.

How Effective Is SUBOXONE?

Buprenorphine, the primary active ingredient in SUBOXONE, has been studied extensively since 1978, when it was first proposed for the treatment of opioid dependence.

A number of clinical trials have established that buprenorphine is effective for:

- Suppressing symptoms of opioid withdrawal
- Reducing cravings for opioids
- Reducing illicit opioid use
- Blocking the effects of other opioids
- Helping patients stay in treatment

In all studies, patients received regular counseling along with their medication.

SUBOXONE, together with counseling, can help you remain in treatment. By having your withdrawal symptoms and cravings better controlled, your overall treatment can focus on resolving issues and gaining skills to avoid **triggers**—situations or stimuli that may cause you to RELAPSE. You can also work with your physician to address issues that may have been contributing to your use of opioids, such as depression, anxiety, or other psychiatric conditions.

How Long Has SUBOXONE Been Used to Treat Opioid Dependence?

SUBOXONE has been available in the United States since 2003. Worldwide, it is estimated that more than 400,000 people had their opioid dependence treated with buprenorphine.

Does SUBOXONE Just Substitute One Dependence for Another?

All opioids can cause physical dependence. But as you've seen in "What Is a Partial Opioid Agonist?" on page 10, the peak level of euphoria experienced with SUBOXONE is limited compared with that of full agonists such as heroin. This experience has been associated with a lower level of physical dependence and limited development of tolerance compared with a full agonist. SUBOXONE provides a level of reinforcement that assists in retaining patients in treatment, including counseling.

When you no longer need SUBOXONE, your dose can be tapered slowly until medication is not required. You and your doctor will discuss the timing and appropriateness of tapering your doses. The withdrawal symptoms of SUBOXONE are milder than those experienced with a full opioid agonist and can be managed with your doctor's supervision.

Please see attached full Prescribing Information.

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Why Is It Important to Take SUBOXONE as Directed?

It is important that you take your SUBOXONE or Subutex® (buprenorphine HCl sublingual tablets) with your other medications exactly as directed by your physician. Abuse or misuse of your medications while on SUBOXONE or Subutex can cause death.

A number of deaths have occurred when dependent people have injected buprenorphine, usually together with benzodiazepines. While you are being treated with SUBOXONE or Subutex, do not use benzodiazepines, tranquilizers, or sedatives unless they have been prescribed by your doctor. Do not drink alcohol while taking SUBOXONE or Subutex.

Can I Switch From Methadone to SUBOXONE?

It is possible to switch to SUBOXONE from methadone treatment. Everyone's situation is different, so talk to your doctor first to see if switching is right for you.

How Long Will I Stay on SUBOXONE?

The length of therapy is up to your doctor, you, and, sometimes, your therapist or counselor.

Although short-term treatment may be an effective option for some people, it may not allow others enough time to address the psychological and behavioral components of their disease. Since physical dependence is only part of opioid dependence, the chance of relapsing can be higher with short-term treatment because patients have less time to learn the skills necessary to maintain an opioid-free lifestyle. Suppressing cravings with SUBOXONE (for as long as you need), combined with counseling and/or support, can often increase the level of treatment success.

Stopping SUBOXONE abruptly will probably cause withdrawal symptoms. When you are ready, your doctor will work with you to taper the doses down to where you can stop taking SUBOXONE. You should be aware of signs of relapse or withdrawal symptoms. If you do discontinue taking SUBOXONE, your leftover pills should be discarded to ensure that they can't be used by anyone else.

Where Can I Find a Physician Who Can Prescribe SUBOXONE?

Doctors 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 the privacy of their office. Ask your doctor if he or she is certified. If not, your doctor may elect to become certified so that he or she can treat you, or your doctor may refer you to a colleague who is certified. You may also be able to find a physician who can treat you with SUBOXONE by calling your local hospital or mental health center and asking them if they have any doctors certified to use SUBOXONE to treat opioid dependence.

Many certified physicians are listed on the *Physician Locator* that you can access at:

- buprenorphine.samhsa.gov/bwns_locator/index.html
- suboxone.com

What Will My Course of SUBOXONE Treatment Be Like?

How Do I Start SUBOXONE Therapy?

Once arrangements have been made for your appointment, your doctor will ask you to arrive in a state of mild-to-moderate withdrawal. Your doctor or the nurse may ask you questions to better evaluate your history of dependence in order to provide you with the best treatment. The information you give will be held strictly confidential. You may also have blood drawn and be asked to provide a urine sample.

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Why Do I Need to Be in Withdrawal?

It is important to be in mild-to-moderate withdrawal when you take your first dose of SUBOXONE because if you have high levels of other opioids in your system, SUBOXONE will compete with the other opioid molecules and knock them off the receptors. SUBOXONE will then replace those opioid molecules on the receptors. Because SUBOXONE has less opioid effects than full opioid agonists, you may go into withdrawal and feel sick. This is called **precipitated withdrawal**. By already being in the first stages of withdrawal when you take your first dose of SUBOXONE, the process will be easier, and SUBOXONE should make you feel better. Once your doctor has assessed your level of withdrawal and decided that you are ready to start SUBOXONE, you will begin the **induction** phase of treatment.

What Happens During Induction?

Your doctor or nurse will give you your first dose in their office. After that, they may have you either stay in the waiting area or take some time away from the office and return at a particular time. At that point, your doctor will assess your withdrawal symptoms and may have you take an additional dose of medication if you are still not feeling well.

When you are ready to leave the office:

- Generally, your doctor will make arrangements for you to have SUBOXONE to take home. Typically, your doctor will give you a prescription for the amount of SUBOXONE that you will need until your next appointment, along with special instructions related to your care
- Your doctor may also prescribe other medications to help control specific withdrawal symptoms
  - You may be asked to return to the office over the next several days in order to assess your symptoms and adjust your dosage. When your opioid receptors are filled with buprenorphine and your symptoms are controlled, your doctor will decide what your regular daily dose of SUBOXONE should be. Once your dose is established, you will begin the **maintenance** phase of treatment
  - At this point, you and your physician may discuss the possibility of beginning medical withdrawal (detox) and explore other posttreatment options

What Happens in the Maintenance Phase?

- When you are receiving a stable daily dose of SUBOXONE and your condition is considered stable (your withdrawal symptoms are relieved and your cravings are decreased or are gone altogether), your doctor may decide to see you less often
- You and your doctor will discuss counseling options that meet your needs
- Your doctor may request urine samples from time to time. Some doctors find urine testing a helpful part of treatment because they can use the results to verify the absence of opioids in your system and thus evaluate the effectiveness of your SUBOXONE dose. You can talk with your doctor about the role of urine testing in SUBOXONE treatment
- During your ongoing maintenance treatment, your doctor will want to know if you experience any withdrawal symptoms. If you do, your dose may need to be adjusted

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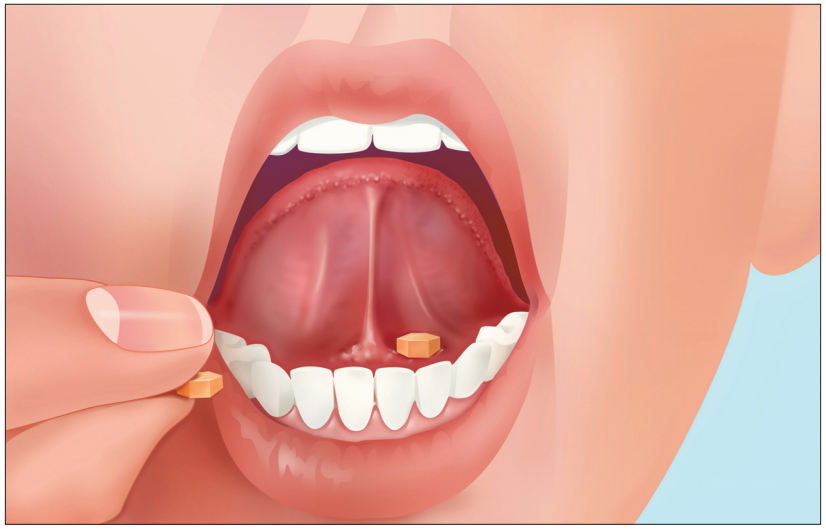
Points to Consider During Maintenance:

- If you miss a dose of SUBOXONE, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and take the next dose at the regular time, unless your doctor instructs you otherwise
- Injecting SUBOXONE is dangerous and can cause severe withdrawal symptoms, painful or collapsed veins, blood clots, and increased risk of infection
- Your friends and family should be advised that an ambulance should be called right away in the rare event that you become extremely sleepy, the pupils of your eyes become like pinpoints, you feel faint or dizzy, or your breathing becomes much slower than normal
- Serious **overdose** and death may occur if benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol are taken at the same time as SUBOXONE or Subutex® (buprenorphine HCl sublingual tablets). Please see information on pages 16 and 22

How Do I Take SUBOXONE?

- Always take your SUBOXONE exactly as prescribed by your doctor
- Before taking SUBOXONE, it's a good idea to drink some water to moisten your mouth. This helps the SUBOXONE tablets dissolve more easily
- If your dose is 1 SUBOXONE tablet, place it under your tongue, lean your head slightly forward, and let the tablet dissolve completely. SUBOXONE is absorbed into the bloodstream through the veins under the tongue
- If your dose is 2 tablets, place both of them under your tongue, 1 on the left side and 1 on the right side (you can use a mirror to make sure the tablets are in the proper places). Lean your head slightly forward and let the tablets dissolve completely
  - If you have more than 2 tablets to take, put the next tablet(s) under your tongue *after* the first tablets have dissolved completely



SUBOXONE enters the bloodstream from under the tongue.

- SUBOXONE takes a short time (about 5 to 10 minutes, but sometimes more) to dissolve completely. Don't chew or swallow the tablets, because less SUBOXONE will be absorbed into your bloodstream, it will not work as well, and your withdrawal symptoms could worsen
- Talking while the tablets are dissolving can interfere with how well SUBOXONE is absorbed
  - You may want to do something that doesn't require talking, such as reading or watching television, while waiting for the tablets to dissolve
  - Let family and friends know that you won't be able to answer them or talk on the phone during this time

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What Safety Information Should I Know About SUBOXONE?

What Are Some Important Directions About SUBOXONE Use?

Intravenous misuse of buprenorphine, usually in combination with benzodiazepines or other CNS depressants, has been associated with significant respiratory depression and death.

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 than prescribed by your doctor. Mixing these drugs can lead to drowsiness, sedation, unconsciousness, and death, especially if injected. It is important to let your doctor know about all medications and substances you are taking. Your doctor can provide guidance if any of these medications are prescribed for the treatment of other medical conditions you may have.

Potential for Dependence

SUBOXONE and Subutex® C (buprenorphine HCl sublingual tablets) have potential for abuse and produce dependence of the opioid type with a milder withdrawal syndrome than full agonists.

Contact Your Doctor if

- You feel faint, dizzy, confused, or have any other unusual symptoms, or if your breathing becomes much slower than normal. These can be signs of taking too much SUBOXONE or of other serious problems
- You experience an allergic reaction. Symptoms of a bad allergic reaction include difficulty breathing, hives, swelling of your face, asthma (wheezing), or shock (loss of blood pressure and consciousness)
- You suspect liver problems due to any of these symptoms:
  - Your skin or the white part of your eyes turns yellow (jaundice)
  - Your urine turns dark
  - Your bowel movements (stools) turn light in color
  - You don't feel like eating much food for several days or longer
  - You feel sick to your stomach (nauseated)
  - You have lower stomach pain

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

Your doctor may do blood tests while you are taking SUBOXONE to ensure that your liver is okay.

- You've recently experienced a head injury (SUBOXONE can alter pupil size and cause changes in the level of consciousness that may interfere with patient evaluation)

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 your doctor determines that the potential benefit to you justifies the potential risk to your unborn child. Contraception should be used while taking SUBOXONE. If you are considering becoming pregnant or do become pregnant while taking SUBOXONE, consult your doctor immediately.

Many women also have changes in menstruation when they use opioids. This may continue while you are taking SUBOXONE. It is important to remember that you can still become pregnant even with irregular periods.

These pages contain a summary of safety information. To find out more, please read the full Prescribing Information attached or ask your doctor or pharmacist.

Suboxone® (buprenorphine HCl/naloxone HCl dihydrate) C sublingual tablets

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What Safety Information Should I Know About SUBOXONE? (cont)

Breast-feeding

Buprenorphine will pass through a mother's milk and may harm the baby, so SUBOXONE is not recommended if you are breast-feeding. Your doctor should know if you are breast-feeding before you start treatment for opioid dependence.

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 your dose is being changed, but can also occur if you drink alcohol or take other sedative drugs when you are on SUBOXONE. Due 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 (36%, placebo 22%), withdrawal syndrome (25%, placebo 37%), pain (22%, placebo 19%), nausea (15%, placebo 11%), insomnia (14%, placebo 16%), and sweating (14%, placebo 10%). You may already be experiencing some of these side effects because of your current use of opioids. If so, let your doctor know. Your doctor can effectively treat many of these symptoms.

SUBOXONE can cause blood pressure to drop. This can cause you to feel dizzy if you get up too fast from sitting or lying down.

Your doctor will determine if you need to stop taking SUBOXONE due to side effects.

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.

Accidental overdose in children is dangerous and can result in death.

Appropriate Use of SUBOXONE

Do not use SUBOXONE or Subutex® Ⓒ (buprenorphine HCl sublingual tablets) for conditions for which they were not prescribed. Patients with a clinical need for analgesia should not be transferred to SUBOXONE. SUBOXONE is not indicated for pain management.

Do not give your medication to other people, even if they have the same symptoms that you have. Sharing is illegal and may cause severe medical problems.

How Can I Increase My Chance of Success With SUBOXONE?

It is important that you communicate openly and honestly with your entire healthcare team (your doctor, nurse, and counselor) to optimize the success of your treatment for opioid dependence. They have been trained to understand opioid dependence and how best to treat this medical condition.

Tools for Success

Patient Diary

To help chart your day-to-day progress, a Patient Diary has been provided on pages 28 and 29 of this brochure. Use this to note how you feel during your SUBOXONE treatment or any changes you are noticing over time.

Patient Emergency ID Card

Keep this card in your wallet so that, in case of an emergency, medical personnel are aware that you are on SUBOXONE and can care for you appropriately.

SUBOXONE is available in 2 dosage strengths: 2 mg buprenorphine with 0.5 mg naloxone, and 8 mg buprenorphine with 2 mg naloxone.

These pages contain a summary of safety information. To find out more, please read the full Prescribing Information attached or ask your doctor or pharmacist.

Suboxone®
(buprenorphine HCl/naloxone HCl dihydrate) Ⓒ sublingual tablets

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Glossary

Agonist: A drug or medication that can interact with receptors to stimulate drug actions or effects.

> **full opioid agonist**: A drug or medication that stimulates activity at opioid receptors in the brain that are normally stimulated by naturally occurring opioids. Examples of full opioid agonists include morphine, methadone, oxycodone, hydrocodone, heroin, codeine, meperidine, propoxyphene, and fentanyl.
> **partial opioid agonist**: A drug or medication that can both activate and block opioid receptors, depending on the clinical situation. Under appropriate conditions, partial agonists can produce effects similar to either agonists or antagonists. Buprenorphine is a partial opioid agonist.

Antagonist: A drug or medication that prevents molecules of other drugs/medications from binding to a receptor (eg, an opioid receptor). Antagonists can also displace other opioids, precipitate withdrawal, or block the effects of other opioids. Examples of antagonists include naltrexone and naloxone.

Craving: The intense desire for something (also called "psychological dependence").

Dependence (physical or psychological): As a general term, the state of needing or depending on something or someone for support or to function or survive. As applied to alcohol and other drugs, the term implies a need for repeated doses of the drug to feel good or to avoid feeling bad. In the DSM-IV, dependence is defined as "a cluster of cognitive, behavioral and physiologic symptoms that indicate a person has impaired control of psychoactive substance use and continues use of the substance despite adverse consequences."

Being compelled to keep using a drug — even when you realize that you have a physical or psychological problem that is probably caused or made worse by the drug.

Dopamine: A naturally occurring chemical that helps cause feelings of pleasure in the brain. Opioid agonists stimulate dopamine activity.

Euphoria: A feeling of pleasure or of being "high."

Induction: The first phase of treatment, when SUBOXONE is given to ease a person's withdrawal symptoms. Induction usually lasts 1 to 5 days.

Maintenance: The phase of treatment when the person is taking a stable dose and working with a physician or counselor to address other issues affecting his/her dependence and ability to rebuild his/her life.

Opioid Dependence: A chronic brain disease that involves a physical, psychological, and behavioral need for an opioid drug. This need is unrelated to medical necessity for pain relief.

Opioid Receptors: Specific places in the brain where molecules of opioid drugs or medications attach and start to exert their effect.

Overdose: When a chemical substance is taken in quantities or concentrations that are large enough to overwhelm the body, causing life-threatening illness or death.

Precipitated Withdrawal: Withdrawal symptoms that result when one drug displaces another drug from the receptor, and the drug has no or less effect than the drug it displaced. When SUBOXONE is given before you are in mild-to-moderate withdrawal from the opioid you have already taken, it can cause withdrawal to occur more rapidly and intensely.

Tolerance: A decrease in response to a drug dose that occurs with continued use. An increase in the dose of the drug is required to achieve the effects originally produced by lower doses.

Triggers: Activities, sounds, places, people, images, events, or other things that may cause a dependent person to want to have the pleasurable feeling of the misused drug or medication again. Triggers can bring on cravings.

Withdrawal: The uncomfortable symptoms (such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, cravings) that develop when a person stops taking a drug or medication on which he or she has become dependent.

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Patient Diary

Date	*Time*	*Dose*	*Changes I've Noticed*

Date	*Time*	*Dose*	*Changes I've Noticed*

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Resources

Web sites that can provide more information about opioid dependence and SUBOXONE treatment:

- suboxone.com
- OpioidDependence.com
- buprenorphine.samhsa.gov
  (the Substance Abuse and Mental Health Services Administration buprenorphine Web site)

In addition, the SUBOXONE Help Line is available from 8 AM to 8 PM EST, Monday through Friday, at 1-877-SUBOXONE (1-877-782-6966).

Emergency Information Wallet Card

Attention Healthcare Provider

This patient is taking SUBOXONE® (buprenorphine HCl/naloxone HCl dihydrate sublingual tablets). Buprenorphine is a partial opioid agonist.

Name of physician: _____

Physician's phone number: _____

Patient's name: _____

Patient's phone number: _____

In an emergency, call 911 for an ambulance.
For further information, call the SUBOXONE Help Line at:
1-877-SUBOXONE (1-877-782-6966)

((Prescribing Information here))

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