**Psychiatry, Psychology, and Psychotherapy**
**Mark Kosins, MD * Michael Roham, PA-C**
647 Camino De Los Mares #200
San Clemente, CA 92673
(PH) 949489 9898 * (FAX) 949 489 2569

# BUPRENORPHINE MAINTENANCE TREATMENT
# INFORMATION FOR PATIENTS

*Specific information for patients who are considering treatment with buprenorphine*

## BUPRENORPHINE – A NEW TREATMENT FOR HEROIN ADDICTION

Addiction medicine doctors consider addiction to be a chronic disease and treat it accordingly. Buprenorphine is one of the medications, which can be used to treat opioid addiction. Opioids are drugs like heroin, opium, morphine, codeine, oxycodone, hydrocodone, etc., which can be abused and lead to tolerance and dependence. This means that the user's body becomes accustomed to ever-higher amounts, and, when the drug is stopped, there are symptoms of withdrawal. Even after the worst physical part of withdrawal is over, some patients still don't feel right for a long time and may relapse to using drugs again, just to "feel normal."

Some of the medical research shows that after abusing drugs for a long time the brain is thrown off balance, and the goal of treatment is to encourage stability, both in the body and in the patient's life.

Not all patients who abuse opioids need medication to treat their addiction. Many addicted persons do very well with counseling, or residential therapeutic treatment, or in NA groups. But in some cases these approaches alone are not enough to keep the person stable, and maintenance medication is used. Maintenance medication is slower and longer acting in its effects on the brain than heroin or other drugs of abuse. This allows for a steadying of brain function, which is part of treatment. So the best way to use buprenorphine in maintenance treatment is to find the correct dose, where the patient feels normal, and keep that dose steady for a long time. This means taking the medication on a regular schedule as prescribed, in the same way as taking a blood pressure medication, or diabetes treatment.

Besides buprenorphine, there are two other maintenance medications, which are used to treat addiction: methadone and LAAM. These medications are also long acting and work by stabilizing the brain. These medications are given in specially licensed clinics called Opioid Treatment Programs, and their use is carefully regulated by federal and state agencies.

Buprenorphine also is bound by some regulations. For this reason, patients on buprenorphine will be asked to give urines for drug screens, and bring their bottles in for pill counts.

Buprenorphine is best started when the patient is suffering withdrawal, and the dose is adjusted over several days. It is given as a pill, which dissolves under the tongue. The take-home buprenorphine pills also have a small amount of naloxone (Narcan) in them, which is an opioid antagonist. The purpose of the naloxone is to discourage illicit injection of the pill. The patient would not feel the effects of naloxone by mouth, but if it were dissolved and injected, it might cause severe withdrawal.

### What happens when the treatment with buprenorphine doesn't work?

Buprenorphine treatment may be discontinued for several reasons. Here are some examples:

- Buprenorphine controls withdrawal symptoms and is an excellent maintenance treatment for many patients, but some patients may need a stronger maintenance medication. If you are unable to control your heroin abuse, or if you continue to feel like using, even at the top doses of buprenorphine, then the doctor may advise you to transfer to methadone or LAAN at a clinic licensed to give those treatments.
- There are certain rules and patient agreements that are part of buprenorphine treatment, which are signed by all patients on admission. If you do not keep these agreements, you may be discharged from buprenorphine treatment.
- Prompt payment of clinic fees is part of buprenorphine treatment. If you cannot pay your fees, please discuss arranging a payment plan. If you still cannot pay, you will be discharged from buprenorphine.
- Dangerous or inappropriate behavior that is disruptive to the clinic or to other patients will result in discharge from buprenorphine treatment. This includes patients who come to the clinic intoxicated or loaded.
- Obviously, in the rare case of allergic reaction to the medication, it has to be discontinued.

The usual method of ending treatment is a taper, which means a decreasing dose of buprenorphine over a two-week period. After this time, you would no longer be enrolled in the buprenorphine program, and your treatment slot would be used for another patient. In some cases, a direct transfer to another kind of maintenance treatment can be made, such as to methadone maintenance at a clinic with a special license to use methadone to treat addiction.

In the case of dangerous behavior, there will be no two-week taper, and the patient will be summarily discharged and asked not to return.

## BUPRENORPHINE MAINTENANCE TREATMENT

## INFORMATION for PATIENTS

*General overview information geared for methadone maintenance patients, but useful for anyone*

## NEW TREATMENT FOR HEROIN ADDICTION

We would like to inform our patients about a new treatment for heroin addiction, which has recently become legal, but is not yet available, (the Drug Addiction Treatment Act of 2000, signed by President Clinton on October 17). This law has several "firsts". For the first time, a physician in the office setting will be able to prescribe a narcotic for treatment of addiction - following certain guidelines and restrictions. For the first time a patient who is addicted to heroin will be able to receive opioid medication for detoxification or for maintenance - again with certain restrictions - in a regular office setting, outside of the methadone treatment program. The only medication allowed is buprenorphine. Methadone and LAAM still may not be prescribed in California in an office setting for the treatment of addiction.

***THE NEW LAW: The Drug Addiction Treatment Act of 2000 (DATA)***
***The new law has the following restrictions:***

- The physician has to have training in opioid addiction treatment.
- The physician has to register with the Secretary of Health and Human Services
- The physician will receive a special number to add to his or her DEA license to prescribe scheduled drugs
- The drug prescribed has to be approved by the FDA as useful in the treatment of addiction. (Buprenorphine has been shown to be effective for heroin addiction, and is expected to be approved by FDA.)
- The drug prescribed may not be a Schedule II narcotic, but only III, IV or V. (Buprenorphine is not Schedule II. Methadone and LAAM are.)
- The physician may only have 30 patients on this treatment at one time.
- The physician must have access to counseling services for the addicted patient.

THE NEW MEDICATION: BUPRENORPHINE

Buprenorphine is an opioid medication, which has been used as an injection for treatment of pain while patients are hospitalized, for example for surgical patients. It is a long acting medication, and binds for a long time to the "*mu*" endorphin receptor. This means most patients don't have to take medication every day. It is not absorbed very well orally (by swallowing) – so a sublingual (dissolve under the tongue) tablet has been developed for treatment of addiction. One form of this sublingual tablet also contains a small amount of naloxone (Narcan), which is an opioid antagonist and will cause withdrawal if injected. Buprenorphine without naloxone has been available in other countries, and has been used illicitly by addicted persons, but so far it hasn't been abused when combined with naloxone.

***Aside from being mixed with naloxone to discourage needle use, buprenorphine itself has a "ceiling" of narcotic effects (it is considered a "partial agonist") which makes it safer in case of overdose. This means that by itself, even in large doses, it doesn't suppress breathing to the point of death in the same way that heroin, methadone and LAAM could do in huge doses. If a child swallowed a whole bottle of buprenorphine tablets (remember they are not absorbed very well by swallowing) it would probably not be lethal, whereas a single dose of methadone might be lethal to a child. These are some of the unusual qualities of this medication which make it safer to use outside of the usual strict methadone regulations at a clinic and, after***

***stabilization, most patients would be able to take home as much as four weeks' worth of buprenorphine at a time.***

***WILL BUPRENORPHINE BE USEFUL FOR PATIENTS ON METHADONE?***

Our methadone maintenance patients may be interested in whether this medication might help them. Unfortunately, because of the partial agonist nature of the medication, buprenorphine is not equivalent in maintenance strength to methadone and LAAM. In order to even try buprenorphine without going into major withdrawal, a methadone-maintained patient would have to taper down to 30mg of methadone or lower. We are concerned that this medication may not be strong enough for most of our patients, and might lead to dangerous relapses if attempted**. If you decide to try it, please be aware of this danger of relapse**, and keep the door open for resuming methadone immediately if necessary.

There are also some studies which show that detoxification from buprenorphine is effective. Some patients may decide to use buprenorphine to detoxify from heroin, instead of the usual methadone detoxification treatment. So far we don't know whether buprenorphine will be "covered" under Medi-Cal (Medicaid) the way methadone detoxification frequently is.

So far, remember the following tips:

- If you are offered buprenorphine by a "friend" and you are taking methadone or LAAM, the buprenorphine will push the other opioids off the receptor site, and you may be in withdrawal and very uncomfortable.
- If you dissolve and inject the buprenorphine-naloxone sublingual tablet it may induce severe withdrawal because of the naloxone, which is an antagonist.
- If you are on methadone treatment and wish to transfer to buprenorphine, your dose has to be at or below 30mg.
- There have been deaths reported when buprenorphine is combined with benzodiazepines. (This family of drugs includes Klonopin, Ativan, Halcion, Valium, Xanax, Librium, etc.) If you are taking any of these drugs, either by prescription or on your own, buprenorphine is may not be a good treatment for you.

**MORE INFORMATION TO COME**

We will keep you posted as more practical facts develop about the use of this new treatment.

**BUPRENORPHINE MAINTENANCE TREATMENT**
**INFORMATION for FAMILY MEMBERS**

Family members of patients who have been prescribed buprenorphine for treatment of addiction often have questions about this treatment.

**What is an opioid?**
Opioids are addictive narcotics in the same family as opium and heroin. This includes many prescription pain medications, such as Codeine, Vicodin, Demerol, Dilaudid, Morphine, Oxycontin, and Percodan. Methadone, LAAM (short for levo-alpha-acetyl methadol), and buprenorphine are also opioids.

**Why are opioids used to treat addiction?**
Many family members wonder why doctors use buprenorphine to treat opiate addiction, since it is in the same family as heroin. Some of them ask, "Isn't this substituting one addiction for another?" But the three medications used to treat addiction to heroin – methadone, LAAM and buprenorphine – are not "just substitution." Many medical studies since 1965 show that maintenance treatment helps keep patients healthier, keeps them from getting into legal troubles, and prevents them from getting AIDS.

**What is the right dose of buprenorphine?**
Family members of patients who have been addicted to heroin have watched as their loved ones use a drug that makes them high, or loaded, or have watched the painful withdrawal which occurs when the drug is not available. Sometimes the family has not seen the 'normal' person for years. They may have seen the patient misuse doctors' prescriptions for narcotics to get high. They are rightly concerned that the patient might misuse or take too much of the buprenorphine prescribed by the doctor. They may watch the patient and notice that the patient seems drowsy, or stimulated, or restless, and think that the buprenorphine will be just as bad as heroin.

Every opioid can have stimulating or sedating effects, especially in the first weeks of treatment. The 'right' dose of buprenorphine is the one that allows the patient to feel and act normally. It can sometimes take a few weeks to find the right dose. During the first few weeks, the dose may be too high, or too low, which can lead to withdrawal, daytime sleepiness, or trouble sleeping at night. The patient may ask that family members help keep track of the timing of these symptoms, and write them down. Then the doctor can use all these clues to adjust the amount and time of day for buprenorphine doses.

Once the right dose is found, it is important to take it on time in a regular way, so the patient's body and brain can work well.

**How can the family support good treatment?**
Even though maintenance treatment for heroin addiction works very well, it is NOT a cure. This means that the patient will continue to need the stable dose of buprenorphine, with regular monitoring by the doctor. This is similar to other chronic diseases, such as diabetes, or asthma. These illnesses can be treated, but there is no permanent cure, so patients often stay on the same medication for a long time. The best way to help and support the patient is to encourage regular medical care, and encourage the patient not to skip or forget to take the medication.

- **<u>Regular medical care</u>**
Most patients will be required to see the physician for ongoing buprenorphine treatment every two to four weeks, once they are stable. If they miss an appointment, they may not be able to refill the medication on time,

and may even go into withdrawal, which could be dangerous. The patient will be asked to bring the medication container to each visit, and may be asked to give urine, blood or breath samples at the time of the visit.

**- Special medical care**

Some patient may also need care for other needle-related problems, such as hepatitis, or HIV disease. They may need to go for blood work, or see several physicians for these illnesses.

**- Counseling**

Most patients who are recovering from addiction need counseling at some point in their care. The patient may have regular appointments with an individual counselor, or for group therapy. These appointments are key parts of treatment, and work together with the buprenorphine treatment to improve success in treatment for addiction. Sometimes family members may be asked to join in family therapy sessions, which also are geared to improve addiction care.

**- Meetings**

Most patients use some kind of recovery group to maintain their sobriety. It sometimes takes several visits to different groups to find the right 'home' meeting. In the first year of recovery some patients go to meetings every day, or several times per week. These meetings work to improve success in treatment, in addition to taking buprenorphine. Family members may have their own meetings, such as Al-Anon, or ACA, to support them in adjusting to life with a patient who has addiction.

**- Taking the medication**

Buprenorphine is unusual because it must be dissolved under the tongue, rather than swallowed. Please be aware that **this takes a few minutes.** While the medication is dissolving, the patient will not be able to answer the phone, or the doorbell, or speak very easily. This means that the family will get used to the patient being 'out of commission' for a few minutes whenever the regular dose is scheduled.

**- Storing the medication**

If buprenorphine is lost or misplaced, the patient may skip doses or go into withdrawal, so it is very important to find a good place to keep the medication safely at home – away from children or pets, and always in the same location, so it can be easily found. The doctor may give the patient a few 'backup' pills, in a separate bottle, in case an appointment has to be rescheduled, or there is an emergency of some kind. It is best if the location of the buprenorphine is NOT next to the vitamins, or the aspirin, or other over-the-counter medications, to avoid confusion. If a family member or visitor takes buprenorphine by mistake a physician should check him or her immediately.

**What does buprenorphine treatment mean to the family?**

It is hard for any family when a member finds out he or she has a disease that is not curable. This is true for addiction as well. When chronic diseases go untreated, they have severe complications, which lead to disability and death. Fortunately, buprenorphine maintenance can be a successful treatment, especially if it is integrated with counseling and support for life changes that the patient has to make to remain 'clean and sober.'

Chronic disease means the disease is there every day, and must be treated every day. This takes time and attention away from other things, and family members may resent the effort and time and money that it takes for buprenorphine treatment and counseling. It might help to compare addiction to other chronic diseases, like diabetes or high blood pressure. After all, it takes time to make appointments to go to the doctor for blood pressure checks, and it may annoy the family if the food has to be low in cholesterol, or unsalted. But most families can adjust to these changes, when they consider that it may prevent a heart attack or a stroke for their loved one.

Another very important issue for family members to know about is: addiction can be partly inherited. Research is showing that some persons have more risk for becoming addicted than others, and that some of this risk is genetic. So when one member develops heroin addiction, it means that other blood relatives should consider themselves 'at risk' of developing addiction or alcoholism. It is especially important for young people to know that alcohol or drugs at parties might be dangerous for them, even more than to most of their friends.

It is common for people to think of addiction as a weakness in character, instead of a disease. Perhaps the first few times the person used drugs it was poor judgment. However, by the time the patient is addicted, and using every day, and needing medical treatment, it can be considered to be a 'brain disease' rather than a problem with willpower. In fact, research brain scans that are done in patients who are on maintenance start to look normal again with treatment.

Sometimes when the patient improves and starts feeling normal, the family has to get used to the new "normal" person. The family interactions (sometimes called 'family dynamics', or 'system') might have been all about trying to help this person in trouble, and now he or she is no longer in so much trouble. Some families can use some help themselves during this change, and might ask for family therapy for a while.

**In summary:**
Family support can be very helpful to patients on buprenorphine treatment. It helps if the family members understand how addiction is a chronic disease that requires ongoing care. It also helps if the family gets to know a little about how the medication works, and how it should be stored at home to keep it safe. Family life might have to change to allow time and effort for 'recovery work' in addiction treatment. Sometimes family members themselves can benefit from therapy.

## PATIENT INFORMATION

**Suboxone®** (sub-OX-own)
(buprenorphine HCI/naloxone HCI dihydrate, sublingual tablet) (C*)

**Subutex®** (SUB-u-tex)
(buprenorphine HCI, sublingual tablet) (C*)

**Read this information carefully before you take SUBOXONE or SUBUTEX and each time you get more SUBOXONE or SUBUTEX.** There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment. Only you and your doctor can decide if SUBONONE or SUBUTEX is right for you. Share important information in this leaflet with members of your household.

**What is the most important information I should know about SUBOXONE and SUBUTEX?**

- **SUBOXONE and SUBUTEX can cause death from overdose,** especially if you inject them with tranquilizers. Use SUBOXONE or SUBUTEX **exactly** the way your doctor tells you to with medicines used to treat depression or anxiety.
- **Use SUBOXONE and SUBUTEX only for the condition for which it was prescribed**
- **SUBOXONE and SUBUTEX can cause drug dependence.** This means that you can get withdrawal symptoms if you stop using the medication too quickly. SUBOXONE and SUBUTEX are not for occasional ("as needed") use.
- **Prevent theft and misuse.** SUBOXONE and SUBUTEX contain a narcotic painkiller that can be a target for people to abuse prescription medicines or street drugs. Therefore, keep your tablets in a safe place to protect them from theft. **NEVER** give them to anyone else. Selling or giving away this medication is against the law.
- **In an emergency**, have family members tell emergency room staff that you are dependent on opioids (narcotic painkillers) and are being treated with SUBOXONE or SUBUTEX.

**What are SUBOXONE and SUBUTEX?**

SUBOXONE and SUBUTEX are prescription medicines used to treat adults addicted to opioid (narcotic painkillers) medicines and drugs, such as morphine and heroin. SUBOXONE and SUBUTEX take the place of these medicines and drugs and may help you stop using and abusing them. SUBOXONE and SUBUTEX are part of a complete addiction treatment program that also includes counseling or behavioral therapy.
**SUBOXONE and SUBUTEX have not been studied in children.**

**SUBOXONE** is a tablet that contains 2 medicines:

1. The first medicine is called buprenorphine (BYOO-pruh-NOR-feen). It is like painkiller medicines, such as morphine, street drugs like heroin, and addiction treatment medicines like methadone. Buprenorphine may give you less of a "high" than these other prescription medications and street drugs. Withdrawal or stopping buprenorphine may be easier than stopping other prescription medicines and street drugs.

2. SUBOXONE also contains naloxone (nal-OX-own). When naloxone is injected, it blocks the effects of medicines and drugs like methadone, heroin, and morphine. Naloxone is added to the SUBOXONE to stop people from injecting ("shooting up") SUBOXONE tablets. When you use SUBOXONE under your tongue (sublingually), as prescribed, the naloxone in SUBOXONE should not stop the medicine's effect. However, if you inject SUBOXONE, the naloxone can give you bad withdrawal symptoms.

**SUBUTEX** is a tablet and it contains only the medicine buprenorphine (see "What is SUBOXONE?" for a description of buprenorphine). SUBUTEX is different from SUBOXONE because it does not contain naloxone. It is usually used under a doctor's direct supervision.

**Who should not take SUBOXONE or SUBUTEX?**

**DO not take SUBOXONE or SUBUTEX if:**

- Your doctor did not prescribe SUBUTEX or SUBOXONE for you.
- You are allergic to buprenorohine, or any of the active ingredients in the medicines. (See the end of this leaflet for a complete list of ingredients)

**Do not take SUBOXONE if:**

- You are allergic to naloxone or buprenorphine.

**Your doctor should know about all your medical conditions** before deciding if SUBOXONE or SUBUTEX is right for you or what dose is best. Tell your doctors about all of your medical problems, especially the ones listed below:

- Trouble breathing or lung problems
- Head injury or brain problem
- Liver or kidney problems
- Gallbladder problems
- Adrenal gland problems, such as Addison's disease
- Low thyroid (hypothyroidism)
- Enlarged prostate gland
- Problems urinating
- A curve in your spine that affects breathing
- Severe mental problems or hallucinations (seeing or hearing things that are really not there)
- Alcoholism

If any of these conditions apply to you, make sure you tell your doctor about them **before** taking SUBOXONE or SUBUTEX.

**Tell your doctor:**

- **If you are pregnant or plan to become pregnant.** SUBOXONE or SUBUTEX may not be right for you. It is not known whether SUBOXONE or SUBUTEX could harm your baby.

- **If you are breast-feeding.** SUBOXONE or SUBUTEX will pass through your mile and may harm your baby.

**Tell your doctor about all of the medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements. They may cause serious side effects when taken with SUBOXONE or SUBUTEX. Sometimes, the doses of certain medicines and SUBOXONE or SUBUTEX need to be reduced if used together.

**DO NOT take any other medicine, herbal or over the counter medicines while using SUBOXONE or SUBUTEX unless your doctor has told you it is okay.**

**How should I take SUBOXONE or SUBUTEX?**

- **Follow your doctor's directions EXACTLY.** Your doctor may change your dose after seeing how the medicine affects you. Do not change your does unless your doctor tells you to change it. Do not take SUBOXONE or SUBUTEX more often than prescribed.
- **Put the tablets under your tongue and let them melt.** This will take 2 to 10 minutes. Do not chew or swallow tablets. The medicine will not work this way and you may get withdrawal symptoms.

- **If your doctor tells you to take more than one tablet, you will be told to:**

a. Take all tablets at the same time together under your tongue, or
b. Take 2 tablets, put them under your tongue. After they melt, put the next tablet or tablets under your tongue right away
c. Hold the tablets under your tongue until they melt completely. The medicine will not work if swallowed and you may get withdrawal symptoms.
d. DO NOT CHANGE the way you are told to take your medicine or you may get too little or too much medicine.

- **Do not inject ("shoot-up") SUBOXONE or SUBUTEX.** Shooting-up is dangerous and you may get bad withdrawal symptoms.
- **SUBOXONE and SUBUTEX can cause** withdrawal symptoms if you take them too soon after using drugs like heroin, morphine, or methadone.
- **If you miss a dose** of SUBOXONE or SUBUTEX, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. **Do not take 2 doses at once, unless your doctor tells you to.**
- **Before stopping** SUBOXONE or SUBUTEX, ask your doctor how to stop to avoid withdrawal symptoms.
- **If you take too much** SUBOXONE or SUBUTEX or **overdose,** call your local emergency number or poison control center right away.

**After you stop taking SUBOXONE or SUBUTEX, flush the unused tablets down the toilet.**

**What should I avoid while taking SUBOXONE or SUBUTEX?**

- **Do not drive, operate heavy machinery, or perform any other dangerous activities** until you know if this medicine effects how alert you are.
- **Do not drink alcohol or take tranquilizers or sedatives** (medicines that help you sleep) while using SUBOXINE or SUBUTEX. **You can die when you use these products with SUBOXONE or SUBUTEX.**

- **Do not take other medicines without talking to your doctor.** Other medicines include prescription and non-prescription medicines, vitamins, and herbal supplements. Be especially careful about medicines that may make you sleepy.

**What are the possible side effects of SUBOXONE and SUBUTEX?**

**Call your doctor or get medical help right away if:**

- You feel faint, dizzy, confused or have any other unusual symptoms.
- Your breathing gets much slower than is normal for you.

**These can be signs of an overdose or serious problem.**

**SUBOXONE and SUBUTEX may cause liver problems.** Call your doctor right away if:

- Your skin or the white parts of your eyes turns yellow (jaundice).
- Your urine turns dark.
- Your bowel movements (stools) turn light in color.
- You feel sick to your stomach (nausea).
- You have lower back pain.

Your doctor will do blood tests while you are taking SUBOXONE or SUBUTEX to make sure your liver is okay.

- **SUBOXONE and SUBUTEX can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.
- **SUBOXONE and SUBUTEX can cause allergic reactions that can make it hard for you to breath.** Other symptoms of a bad allergic reaction include hives, swelling of your face, asthma (wheezing) or shock (loss of blood pressure and consciousness). Call a doctor or get emergency help right away of you get any of these symptoms.

**You may have withdrawal symptoms when you start treatment with SUBOXONE and SUBUTEX.**

You can develop dependence from taking SUBOXONE or SUBUTEX, and so you may get withdrawal symptoms when you stop taking SUBOXONE or SUBUTEX. There is also a chance that you may abuse or get addicted to SUBOXONE or SUBUTEX because SUBOXONE or SUBUTEX are treatments for other drug addictions.

Some of the common side effects of SUBOXONE or SUBUTEX are headache, pain, problems sleeping, nausea, sweating, stomach pain, and constipation.

These are not all the possible side effects of SUBOXONE or SUBUTEX. For a complete list, ask your doctor or pharmacist.

**GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF SUBOXONE AND SUBUTEX.**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use SUBOXONE or SUBUTEX for conditions for which they were not prescribed \. Do not give SUBOXONE or SUBUTEX to other people, even if they have the same symptoms you have. Sharing is illegal and may cause severe medical problems. Keep SUBOXONE and SUBUTEX out of the reach of children. **Accidental overdose in children is dangerous and can result in death.**

This leaflet summarizes the most important information about SUBOXONE and SUBUTEX. If you would like more information, talk with your doctor. Also, you can ask your pharmacist or doctor for information about SUBOXONE and SUBUTEX that is written for health professionals. For more information call 1-877-SUBOXONE (1-877-782-6966), or visit our Web site, www.suboxone.com.

**What are the ingredients of SUBOXONE and SUBUTEX?**

**SUBOXONE:**
**Active Ingredients:** buprenorphine hydrochloride and naloxone hydrochloride dihydrate

**Inactive Ingredients:** lactose, mannitol, cornstarch, povidone K30, citric acid, sodium citrate, FD&C Yellow No. 6 color, magnesium stearate, and for flavoring, Acesulfame K sweetener and a lemon-lime flavor

**SUBUTEX:**
**Active Ingredients:** buprenorphine hydrochloride

**Inactive Ingredients:** lactose, mannitol, cornstarch, povidone K30, citric acid, sodium citrate and magnesium stearate

**Rx ONLY**