

Patient Information Leaflet

PATIENT INFORMATION

SUBOXONE[®] (sub-OX-own)

(buprenorphine HCl/naloxone HCl dihydrate, sublingual tablet) (C*)

SUBUTEX[®] (SUB-u-tex)

(buprenorphine HCl, 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 SUBOXONE or SUBUTEX is right for you. Share the 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 medicine 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 who 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 medicine 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 medicines 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 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 effects. 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 buprenorphine, or any of the inactive 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 doctor 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 (men)
- problems urinating
- a curve in your spine that affects your breathing
- severe mental problems or hallucinations (seeing or hearing things that are not really 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 milk and may harm your baby.

Tell your doctor about all 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 medicine 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 dose 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 the tablets. The medicine will not work this way and you may get withdrawal symptoms.
- **If your doctor tells you to take more than 1 tablet,** you will be told to:
 - take all tablets at the same time together under your tongue, or
 - take 2 tablets, put them under your tongue. After they melt, put the next tablet or tablets under your tongue right away
 - hold the tablets under your tongue until they melt completely. The medicine will not work if swallowed and you may get withdrawal symptoms.
 - 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 affects how alert you are.
- **Do not drink alcohol or take tranquilizers or sedatives** (medicines that help you sleep) while using SUBOXONE 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 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 (nausea).
- You have lower stomach 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 breathe. 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 if you get any of these symptoms.

You may have withdrawal symptoms when you start treatment with SUBOXONE or 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 and SUBUTEX are treatments for other drug addictions.

Some of the common side effects of SUBOXONE and 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