

Information Guide on Suboxone Treatment

What is the most important information I should know about Suboxone (buprenorphine and naloxone)?

Buprenorphine and naloxone can cause death from overdose, especially if it is injected with a tranquilizer. Use buprenorphine and naloxone exactly as directed by your doctor.

Buprenorphine and naloxone can cause drug dependence. This means that withdrawal symptoms may occur if you stop using the medicine too quickly. Withdrawal symptoms may also occur at the start of treatment due to dependence on another drug. Buprenorphine and naloxone is not for occasional ("as needed") use. Do not stop taking buprenorphine and naloxone without first talking to your doctor. Your doctor may want to gradually reduce the dose to avoid or minimize withdrawal symptoms.

In an emergency, have family members tell emergency room staff that you are taking buprenorphine and naloxone and that you are dependent on opioids.

Use caution when driving, operating machinery, or performing other hazardous activities. Buprenorphine and naloxone may cause drowsiness, dizziness, or impaired thinking. If you experience drowsiness, dizziness, or impaired thinking, avoid these activities.

Avoid alcohol while taking buprenorphine and naloxone. Alcohol may dangerously increase drowsiness and dizziness caused by the medication.

Buprenorphine and naloxone may dangerously increase the effects of other drugs that cause drowsiness, including antidepressants, alcohol, antihistamines, sedatives (used to treat insomnia), other pain relievers, anxiety medicines, and muscle relaxants. Tell your doctor about all medicines that you are taking, and do not take any other prescription or over-the-counter medicine, including herbal products, without first talking to your doctor.

What is buprenorphine and naloxone?

Buprenorphine is an opioid medication. Buprenorphine is similar to other opioids such as morphine, codeine, and heroin however, it produces less euphoric ("high") effects and therefore may be easier to stop taking.

Naloxone blocks the effects of opioids such as morphine, codeine, and heroin. If buprenorphine and naloxone is injected, naloxone will block the effects of buprenorphine and lead to withdrawal symptoms in a person with an opioid addiction. When administered under the tongue as directed, naloxone will not affect the actions of buprenorphine.

Buprenorphine and naloxone is used to treat Opioid Dependence.

Do not take buprenorphine and naloxone if:

the medication was not prescribed for you; or
you are allergic to buprenorphine, naloxone, or any components of the tablets.

Before taking buprenorphine and naloxone, tell your doctor if you have:

- lung problems or difficulty breathing;
- a head injury or brain problem;
- liver problems;
- kidney problems;
- gallbladder problems;
- adrenal gland problems, such as Addison's disease;
- low thyroid (hypothyroidism);
- enlarged prostate gland;
- problems urinating;
- a curve in the spine that affects breathing;
- severe mental problems or hallucinations (seeing or hearing things that are not really there); or
- alcoholism.

You may not be able to take buprenorphine and naloxone, or you may require a dosage adjustment or special monitoring during treatment if you have any of the conditions listed above.

Buprenorphine and naloxone is in the FDA pregnancy category C. This means that it is not known whether buprenorphine and naloxone will be harmful to an unborn baby. Use of buprenorphine and naloxone during pregnancy may cause withdrawal symptoms in a newborn baby. Do not take buprenorphine and naloxone if you are pregnant or could become pregnant during treatment.

Buprenorphine and naloxone passes into breast milk and may be harmful to a nursing baby. Do not take buprenorphine and naloxone if you are breast-feeding a baby.

How should I take buprenorphine and naloxone?

Take Suboxone (buprenorphine and naloxone) exactly as directed by your doctor. If you do not understand these directions, ask your pharmacist, nurse, or doctor to explain them to you.

Suboxone is for sublingual administration not to be swallowed as it doesn't get absorbed by stomach or intestine.

The buprenorphine and naloxone tablets should be placed under the tongue and allowed to dissolve. This will take 2 to 10 minutes. If more than one tablet is prescribed per dose, your doctor may tell you to put not more than 2 tablets under your tongue and allow them to dissolve completely, then put the next tablet or tablets under the tongue right away. Don't eat or drink for

20 minutes after taking the tablet. You may lose some of your medication if you eat or drink immediately.

Do not chew or swallow the tablets. The medicine will not work this way and you may get withdrawal symptoms.

Do not change the dose of buprenorphine and naloxone or take it more often than prescribed without first talking to your doctor.

Do not inject ("shoot-up") buprenorphine and naloxone. Shooting-up is dangerous and may cause bad withdrawal symptoms.

Buprenorphine and naloxone may cause withdrawal symptoms if taken too soon after a dose of heroin, morphine, or methadone.

Buprenorphine and naloxone can cause drug dependence. This means that withdrawal symptoms may occur if you stop using the medicine too quickly. Withdrawal symptoms may also occur at the start of treatment due to dependence on another drug. Buprenorphine and naloxone is not for occasional ("as needed") use. Do not stop taking buprenorphine and naloxone without first talking to your doctor. Your doctor may want to gradually reduce the dose to avoid or minimize withdrawal symptoms.

When treatment with buprenorphine and naloxone is completed, flush any unused tablets down the toilet.

Buprenorphine and naloxone can cause constipation. Drink plenty of water (six to eight full glasses a day) to lessen this side effect. Increasing the amount of fiber in your diet can also help to alleviate constipation.

Your doctor may want to perform blood tests or other forms of monitoring during treatment with buprenorphine and naloxone.

Store buprenorphine and naloxone at room temperature away from moisture and heat. Buprenorphine and naloxone may be a target for people who abuse prescription or street drugs. Therefore, keep the tablets in a safe place to protect them from theft. Never give them to anyone else. Sell or giving away this medicine is against the law.

What happens if I miss a dose?

Take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take only the next regularly scheduled dose. Do not take a double dose of this medication.

What happens if I overdose?

Seek emergency medical attention.

Symptoms of a buprenorphine and naloxone overdose may include slow breathing, seizures, dizziness, weakness, loss of consciousness, coma, confusion, tiredness, cold and clammy skin, and small pupils.

What should I avoid while taking buprenorphine and naloxone?

In an emergency, have family members tell emergency room staff that you are taking buprenorphine and naloxone and that you are dependent on opioids.

Use caution when driving, operating machinery, or performing other hazardous activities. Buprenorphine and naloxone may cause drowsiness, dizziness, or impaired thinking. If you experience drowsiness, dizziness, or impaired thinking, avoid these activities.

Dizziness may be more likely to occur when rising from a sitting or lying position. Rise slowly to minimize dizziness and prevent a fall.

Avoid alcohol while taking buprenorphine and naloxone. Alcohol may dangerously increase drowsiness and dizziness caused by the medication.

Buprenorphine and naloxone may dangerously increase the effects of other drugs that cause drowsiness, including antidepressants, alcohol, antihistamines, sedatives (used to treat insomnia), other pain relievers, anxiety medicines, and muscle relaxants. Tell your doctor about all medicines that you are taking, and do not take any other prescription or over-the-counter medicine, including herbal products, without first talking to your doctor.

What are the possible side effects of buprenorphine and naloxone?

Buprenorphine and naloxone can cause drug dependence. This means that withdrawal symptoms may occur if you stop using the medicine too quickly. Withdrawal symptoms may also occur at the start of treatment due to dependence on another drug. Buprenorphine and naloxone is not for occasional ("as needed") use. Do not stop taking buprenorphine and naloxone without first talking to your doctor. Your doctor may want to gradually reduce the dose to avoid or minimize withdrawal symptoms.

Seek emergency medical attention or contact your doctor immediately if you experience any of the following serious side effects:

an allergic reaction (difficulty breathing; closing of the throat, swelling of the lips, tongue, or face; or hives);
slow breathing;
dizziness or confusion; or
liver problems such as yellowing of the skin or eyes, dark colored urine, light colored stools (bowel movements), decreased appetite for several days or longer, nausea, or lower stomach pain.

Other less serious side effects may be more likely to occur. Continue to take buprenorphine and naloxone and talk to your doctor if you experience

headache;
pain;
problems sleeping;
nausea;
sweating;
stomach pain; or
constipation.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

What other drugs will affect buprenorphine and naloxone?

Buprenorphine and naloxone can cause death from overdose, especially if it is injected with a tranquilizer. Use buprenorphine and naloxone exactly as directed by your doctor.

Do not take buprenorphine and naloxone without first talking to your doctor if you are taking:

a benzodiazepine such as alprazolam (Xanax), diazepam (Valium), clonazepam (Klonopin), clorazepate (Tranxene), lorazepam (Ativan), chlordiazepoxide (Librium), oxazepam (Serax), triazolam (Halcion), temazepam (Restoril), estazolam (Prosom), quazepam (Doral), or flurazepam (Dalmane);
erythromycin (Ery-Tab, E.E.S., E-Mycin, others) or clarithromycin (Biaxin);
itraconazole (Sporanox) or ketoconazole (Nizoral);
an HIV protease inhibitor such as indinavir (Crixivan), ritonavir (Norvir) or saquinavir (Fortovase, Invirase);
rifampin (Rifadin, Rimactane), rifapentine (Priftin), or rifabutin (Mycobutin);
phenytoin (Dilantin);
carbamazepine (Tegretol);
a barbiturate such as phenobarbital, mephobarbital (Mebaral), and others.

You may not be able to take buprenorphine and naloxone, or you may require a dosage adjustment or special monitoring during treatment if you are taking any of the medications listed above.

Buprenorphine and naloxone may dangerously increase the effects of other drugs that cause drowsiness, including antidepressants, alcohol, antihistamines, sedatives (used to treat insomnia), other pain relievers, anxiety medicines, and muscle relaxants. Tell your doctor about all medicines that you are taking, and do not take any other prescription or over-the-counter medicine, including herbal products, without first talking to your doctor.

Drugs other than those listed here may also interact with buprenorphine and naloxone. Talk to your doctor and pharmacist before taking any prescription or over-the-counter medicines, including herbal products.

Where can I get more information?

Your pharmacist may have additional information about buprenorphine and naloxone written for health professionals.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.