

SUBOXONE[®] Sublingual Tablets

Buprenorphine Hydrochloride + Naloxone Hydrochloride Dihydrate

Consumer Medicine Information

WARNINGS

Hazardous and harmful use

Although SUBOXONE is indicated for the treatment of opioid dependence it still poses risks of hazardous and harmful use which can lead to overdose and death. The doctor will monitor your ongoing risk during treatment with SUBOXONE.

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of SUBOXONE. Talk to your doctor about situations which may increase the risk of respiratory depression.

Concomitant use of medicines affecting the central nervous system, including alcohol

Use of SUBOXONE with anti-anxiety medicines, sedatives, antihistamines, some antidepressants, antipsychotics, cannabis and alcohol may result in profound sedation, respiratory depression, coma and death.

What is in this leaflet?

This leaflet answers some common questions about SUBOXONE. It does not contain all the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SUBOXONE against the benefits you may gain and he/she believes it will help in your treatment.

If you have any concerns about taking SUBOXONE, ask your doctor.

Keep this leaflet. You may want to read it again.

What is SUBOXONE used for?

SUBOXONE is used as part of a medical, social and psychological treatment program for patients dependent on opioids like heroin, morphine, oxycodone or codeine. SUBOXONE is used to help such patients to regain control over their lives.

SUBOXONE tablets contain the active ingredients buprenorphine hydrochloride and naloxone hydrochloride dihydrate. Buprenorphine acts as a substitute for opioids like heroin and it helps withdrawal from opioid over a period of time. When taken sublingually (under the tongue) as prescribed,

naloxone has no effect, as it is very poorly absorbed. However, if SUBOXONE is injected, naloxone will act to block the effects of other opioids like heroin, methadone or morphine, leading to bad withdrawal symptoms. Therefore, naloxone is included in SUBOXONE to discourage misuse by injection, as it can cause very bad withdrawal symptoms.

SUBOXONE should be used exactly as prescribed by your doctor.

Ask your doctor if you have any questions about why SUBOXONE has been prescribed for you.

Before you take SUBOXONE

SUBOXONE is not suitable for everyone.

When you must not take SUBOXONE

- If you are under the age of 16 years.
- If you are allergic to buprenorphine or to naloxone or to any of the other ingredients in this medicine (see Product Description below).
- If you have serious breathing problems.
- If you have serious problems with your liver, or if your doctor detects the development of
- such a problem during treatment.
- If you are intoxicated due to CNS depressant medicines (e.g. tranquillisers, sedative/hypnotics, narcotic analgesics, anti-anxiety medicines, antipsychotics), alcohol or have delirium tremens (the 'shakes' and hallucinations).

- Do not take SUBOXONE if the package is torn, shows signs of tampering or the tablets do not look quite right.

Before you start to use SUBOXONE

Tell your doctor if you have any of the following before treatment, or develop them during treatment, as your doctor may need to adjust your dose of SUBOXONE.

- if you are pregnant
- if you are breastfeeding
- asthma or other breathing problems
- thyroid problems
- prostate problems
- problems with excess alcohol use
- problems with drowsiness
- Adrenal gland problems (e.g. Addison's disease)
- Kyphoscoliosis (hunchback disease)
- low blood pressure
- urination problems
- kidney problems
- liver problems
- if you have head injuries or in a condition where you have increased pressure within your head
- if you have problems related to the biliary tract
- stomach (abdominal) pains
- if you have severe mental problems or hallucinations (seeing or hearing things that are not really there)
- if you have a history of seizures

Some people have died from respiratory failure (inability to breathe) when using benzodiazepines (medicines used to treat anxiety or sleeping problems) at the same time as SUBOXONE.

Whilst you are being treated with SUBOXONE, do not

use benzodiazepines unless they have been prescribed by your doctor.

SUBOXONE may cause fatal respiratory failure if children accidentally ingest it. **Keep this medicine out of reach and sight of children.**

As SUBOXONE contains naloxone, it is highly likely to produce strong opioid withdrawal symptoms if misused as an injection while you are still experiencing the effects of other opioids. When taken sublingually SUBOXONE can cause withdrawal symptoms if you take it less than six hours after you use a short acting opioid (such as morphine or heroin) or less than 24 hours after a long acting opioid (such as methadone).

SUBOXONE can cause drug dependence. This means that you can get withdrawal symptoms if you stop using the medicine too quickly. Withdrawal symptoms may be delayed in some cases.

SUBOXONE is not intended for occasional use and should be taken only as prescribed.

SUBOXONE may cause drowsiness, which may be made worse if you also drink alcohol or take sedatives or anti-anxiety medicines. If you are drowsy, do not drive or operate machinery.

SUBOXONE may cause your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down.

Athletes should be aware that this medicine may cause a positive reaction to "anti-doping" tests.

The safety and effectiveness in patients over 65 years of age have not been established.

Your doctor may ask you to have additional blood tests to see if this medication is right for you.

Taking Other Medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, before you begin treatment with SUBOXONE.

A number of medicines may alter the effects of SUBOXONE. These include:

- certain medicines for treating HIV/AIDS
- certain medicines for treating fungal and bacterial infections
- strong pain killers
- cough medicines containing opioid-related substances
- certain antidepressants including monoamine oxidase inhibitors
- certain medicines used to treat fits or epilepsy (anti-convulsants)
- sedating antihistamines
- sedatives, alcohol
- anti-anxiety medicines
- certain medicines for high blood pressure
- medicines used to treat alcohol dependence
- antipsychotic medicines
- naltrexone

Tell your doctor if you are scheduled to have surgery using a general anaesthetic.

Do not drink alcohol or take medicines that contain alcohol whilst you are being treated with SUBOXONE.

Alcohol and certain other medicines (as listed above) may increase the sedative effects of buprenorphine, which can make driving and operating machinery hazardous.

Some people have died when using sedatives (benzodiazepines) or other depressants or alcohol or other opioids at the same time as SUBOXONE. You should not use benzodiazepines (medicines used to treat anxiety or sleeping problems) whilst you are taking SUBOXONE unless they are prescribed by your doctor.

How to Take SUBOXONE

Do not take SUBOXONE to treat any condition other than the one prescribed for by your doctor.

Do not give SUBOXONE to anyone else, even if their symptoms seem the same as yours. It may harm them.

The tablets are taken sublingually. This means that you place the tablet under your tongue and allow it to dissolve, which may take 2 to 10 minutes. This is the only way the tablets should be taken.

Do not swallow or consume food or drink until the tablet is completely dissolved. You may take the tablets all at once or in two lots, the second after the first lot has dissolved. Do not split or break the tablets.

The tablets will not work if you chew or swallow them whole.

Do not inject SUBOXONE; patients have died from injecting SUBOXONE. Additionally, when injecting SUBOXONE and also taking benzodiazepines (medicines used to treat anxiety or sleeping problems), people were even more likely to die.

How much to take.

SUBOXONE is only for adults and children over the age of 16 years. Your doctor will tell you how much SUBOXONE to take and you should always follow medical advice.

Each SUBOXONE sublingual tablet contains buprenorphine and naloxone. SUBOXONE containing 2mg buprenorphine and 0.5mg naloxone is referred to as the '2mg' tablets and SUBOXONE containing 8mg buprenorphine and 2mg naloxone is referred to as the '8mg' tablets.

On the first day the usual starting dose is 4-8 mg SUBOXONE with an additional 4 mg depending on your needs, as determined by your treating doctor.

- *For patients who are still using short acting opioids such as heroin, morphine, oxycodone or codeine:* when starting treatment, the dose of SUBOXONE should be taken when the first signs of craving appear or at least 6 hours after your last use of opioid or when the first signs of craving appear.
- *For patients receiving methadone:* before beginning treatment with SUBOXONE, your doctor

will probably reduce your dose of methadone to the minimum methadone daily dose that you can tolerate. The first dose of SUBOXONE should preferably be taken when the first signs of craving appear and at least 24 hours after your last dose of methadone.

SUBOXONE may cause withdrawal symptoms if taken too soon after methadone or an illicit opioid.

During your treatment, your doctor may increase your dose of SUBOXONE to a maximum daily dose of 32mg, depending upon your response to treatment.

After a period of successful treatment, your doctor may gradually reduce your dose. Depending on your condition, your dose may continue to be reduced under careful medical supervision, until it is stopped altogether.

Do not suddenly stop taking the tablets, as this may cause withdrawal symptoms.

If you miss a dose of SUBOXONE

If you miss a dose of SUBOXONE, take it as soon as you remember. If you are unsure consult your doctor.

In an emergency

Have family members or friends tell hospital or ambulance staff that you are dependent on opioids (narcotics) and are being treated with SUBOXONE.

If you take too much of SUBOXONE (overdose)

If you think that you or anyone else may have taken too

much SUBOXONE, immediately telephone your doctor or National Poison Centre (in Australia telephone 13 11 26 or in New Zealand telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much SUBOXONE, some of the symptoms which may or may not occur are listed in the Side effects section of this leaflet.

Side effects

Like all medicines, SUBOXONE may have unwanted side effects which may need medical treatment.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Very common side effects reported with the use of SUBOXONE were:

- difficulty sleeping
- headache
- constipation
- nausea
- sweating

Many of the common side effects reported with the use of SUBOXONE were related to opioid withdrawal symptoms, such as:

- anxiety, nervousness, depression, loss of appetite, abnormal thinking, loss of libido, drowsiness, dizziness
- malaise, fatigue,
- pain in the abdomen, back, joints and muscles, leg cramps, muscle weakness,
- flu like symptoms, such as chills, fever, sore throat, coughing, runny nose, watery eyes, sore throat and sweating
- upset stomach and diarrhoea, pins and needles
- vomiting, diarrhea, wind, indigestion
- rash and itching
- difficulty urinating, impotence
- chest pain

Other side effects which have occurred are:

- migraine,
- abnormal vision,
- tremor
- reduced sex drive,
- chest, back, stomach, muscle, joint pain,
- vomiting, decreased weight,
- hives,
- flushing, swelling of the legs and arms,
- cough, respiratory infection
- urinary track infection, vaginal infection
- anaemia
- eye infection
- palpitation
- asthma
- blood in vomit
- jaundice
- swollen joints
- thoughts of suicide

If you think you are experiencing any of the above side effects, or any other side effects, you should tell your doctor immediately.

- **If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.** There have been rare cases of life-threatening severe hypersensitivity reactions with symptoms of severe difficulty in breathing, swelling, of the face, lips, mouth or throat.
- Some serious cases of severe liver problems have occurred during treatment. If you develop severe fatigue, have no appetite or if your skin or eyes look yellow, you have light coloured bowel motions or dark coloured urine, tell your doctor immediately.

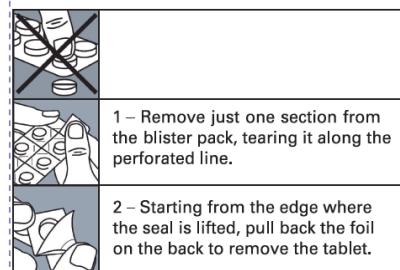
Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After Using SUBOXONE

If you stop taking SUBOXONE and start taking heroin again, you are at risk of being more sensitive to opioids, which could be dangerous. You should talk to your doctor if you start taking heroin again.

Presentation and Storage

SUBOXONE is packed in child resistant blisters. Below are instructions on how to open these blisters.

How to remove the tablet from the blister pack:

Suboxone contains a narcotic 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. Keep out of reach and sight of children. Never give them to anyone else.

The tablets should be stored below 30°C in the original package. SUBOXONE should be protected from moisture and prolonged exposure to light. As with all medicines, keep out of the reach of children. Do not use SUBOXONE after the expiry date that is stamped on the pack.

Product Description

What SUBOXONE Looks Like.

SUBOXONE 2/0.5 are white, hexagonal shaped tablets. Each tablet has a 'N2' on one side.

SUBOXONE 8/2 are white, hexagonal shaped tablets. Each tablet has a 'N8' on one side.

Ingredients:

Each SUBOXONE 2/0.5 sublingual tablet contains 2mg buprenorphine (as the hydrochloride) + 0.5mg naloxone (as the hydrochloride dihydrate) as active ingredients. Each SUBOXONE 8/2 sublingual

tablet contains 8mg buprenorphine (as the hydrochloride) + 2mg naloxone (as the hydrochloride dihydrate) as active ingredients. SUBOXONE 2/0.5 and SUBOXONE 8/2 tablets also contain the following inactive ingredients: lactose monohydrate; mannitol; maize starch; povidone; citric acid; sodium citrate dihydrate, magnesium stearate, acesulfame potassium, and a Lemon and Lime Flavour.

Each pack of SUBOXONE 2/0.5 tablets is labelled with AUST R 120159

Each pack of SUBOXONE 8/2 tablets is labelled with AUST R 120160

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