SUBOXONE® Sublingual Tablets
Buprenorphine Hydrochloride + Naloxone Hydrochloride
Consumer Medicine Information

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. Buprenorphine acts as a substitute for opioids like heroin and it helps withdrawal from opioids 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 you are pregnant. If you become pregnant while taking SUBOXONE tell your doctor.
- Do not take SUBOXONE if you are breastfeeding a baby.
- 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.
- 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
• 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 
der 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 mg 
SUBOXONE but the dose 
will be 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 opioidor 
when the first signs of 
craving appear.

- For patients receiving 
methodone: before 
beginning treatment 
with SUBOXONE, your 
doctor will probably 
reduce your dose of 
methadone to a 
maximum of 30 mg/day. 
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.

Many of the common side effects reported with the use of SUBOXONE were related to opioid withdrawal symptoms, such as:
- difficulty sleeping, anxiety, nervousness
- 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 and sweating,
- upset stomach and diarrhoea.

Other side effects which have occurred are:
- headache, migraine,
- sleepiness, dizziness,
- abnormal vision,
- depression, abnormal thinking, tremor
- difficulty sleeping
- reduced sex drive,
- chest, back, stomach, muscle, joint pain,
- nausea, vomiting, constipation, wind, indigestion, decreased weight,
- hives,
- flushing, swelling of the legs and arms,
- sweating,
- difficulty urinating, impotence
- cough, respiratory infection
- rash and itching.

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.
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 sword logo on one side, with ‘N2’ on the reverse side.

SUBOXONE 8/2 are white, hexagonal shaped tablets. Each tablet has a sword logo on one side, with ‘N8’ on the reverse side.

**Ingredients:**

Each SUBOXONE 2/0.5 sublingual tablet contains 2mg buprenorphine (as the hydrochloride) + 0.5mg naloxone (as the hydrochloride) as active ingredients. Each SUBOXONE 8/2 sublingual tablet contains 8mg buprenorphine (as the hydrochloride) + 2mg naloxone (as the hydrochloride) as active ingredients. SUBOXONE 2/0.5 and SUBOXONE 8/2 tablets also contain the following inactive ingredients: lactose; mannitol; maize starch; povidone; citric acid; sodium citrate, 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

**Sponsor:**

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Auckland 2022

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