

PACKAGE LEAFLET: INFORMATION FOR THE USER

Suboxone 8 mg/2 mg sublingual tablets buprenorphine / naloxone

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What Suboxone is and what it is used for
2. What do you need to know before you take Suboxone
3. How to take Suboxone
4. Possible side effects
5. How to store Suboxone
6. Content of the pack and other information

1. What Suboxone is and what it is used for

Suboxone is used to treat dependence on opioid (narcotic) drugs such as heroin or morphine in drug addicts who have agreed to be treated for their addiction. Suboxone is used in adults and adolescents over 15 years of age, who are also receiving medical, social and psychological support.

2. What do you need to know before you take Suboxone

Do not take Suboxone

- if you are allergic (hypersensitive) to buprenorphine, naloxone or any of the other ingredients of this medicine (see section 6)
- if you have **serious breathing problems**
- if you have **serious liver problems**
- if you are intoxicated due to alcohol or have trembling, sweating, anxiety, confusion, or hallucinations caused by alcohol

Warnings and precautions

Talk to your doctor before taking Suboxone if you have:

- asthma or other breathing problems
- any liver disease such as hepatitis
- low blood pressure
- recently suffered a head injury or brain disease
- a urinary disorder (especially linked to enlarge prostate in men)
- any kidney disease.
- thyroid problems
- adrenocortical disorder (e.g. Addison's disease)

Important things to be aware of:

- **Misuse and abuse**

This medicine can be a target for people who abuse prescription medicines, and should be kept in a safe place to protect it from theft. **Do not give this medicine to anyone else.** It can cause death or otherwise harm them.

- **Breathing problems**

Some people have died from respiratory failure (inability to breathe) because they misused this medicine or took it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.

- **Dependence**

This product can cause dependence.

- **Withdrawal symptoms**

This product can cause withdrawal symptoms if you take it less than six hours after you use a short-acting opioid (e.g. morphine, heroin) or less than 24 hours after you use a long-acting opioid such as methadone.

Suboxone can also cause withdrawal symptoms if you stop taking it abruptly.

- **Liver damage**

Liver damage has been reported after taking Suboxone, especially when the medicine is misused. This could also be due to viral infections (chronic C hepatitis), alcohol abuse, anorexia or use of other medicines with the ability to harm your liver (see section 4). **Regular blood tests may be conducted by your doctor to monitor the condition of your liver. Tell your doctor if you have any liver problems before you start treatment with Suboxone.**

- **Blood pressure**

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

- **Diagnosis of unrelated medical conditions**

This medicine may mask pain symptoms that could assist in the diagnosis of some diseases. Do not forget to advise your doctor if you take this medicine.

Other medicines and Suboxone

Some medicines may increase the side effects of Suboxone and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Suboxone without first talking to your doctor especially:

- **Benzodiazepines** (used to treat anxiety or sleep disorders) such as, diazepam, temazepam, alprazolam. Your doctor will prescribe the correct dose for you. **Taking the wrong dose of benzodiazepines may cause death due to respiratory failure (inability to breathe).**

- **Other medicines that may make you feel sleepy which are** used to treat illnesses such as anxiety, sleeplessness, convulsions/seizures, pain. These types of medicines will reduce your alertness levels making it difficult for you to drive and use machines. They may also cause central nervous system depression, which is very serious. Below is a list of examples of these types of medicines:

- other opioid containing medicines such as methadone, certain pain killers and cough suppressants
- anti-depressants (used to treat depression) such as isocarboxazide, phenelzine, selegeline, tranylcypromine and valproate may increase the effects of this medicine.
- Sedative H₁ receptor antagonists (used to treat allergic reactions) such as diphenhydramine and chlorphenamine.
- Barbiturates (used to cause sleep or sedation) such as Phenobarbital, secobarbital

- Tranquilisers (used to cause sleep or sedation) such as chloral hydrate.
- clonidine (used to treat high blood pressure) may extend the effects of this medicine.
- Anti-retrovirals (used to treat AIDS) such as ritonavir, nelfinavir, indinavir may increase the effects of this medicine.
- Some antifungal agents (used to treat fungal infections) such as ketoconazole, itraconazole, certain antibiotics may extend the effects of this medicine.
- Some medicines may decrease the effect of Suboxone. These include medicines used to treat epilepsy (such as carbamazepine and phenytoin), and medicines used to treat tuberculosis (rifampicin).
- Naltrexone may prevent the therapeutic effects of Suboxone. If currently taking this medicine followed by concomitant use of naltrexone, you may experience a sudden onset of prolonged and intense withdrawal.

To get the greatest benefit from taking Suboxone, you must tell your doctor about all the medicines you are taking, including alcohol, medicines containing alcohol, street drugs, and any prescription medicine you are taking that have not been prescribed to you by your doctor.

Suboxone with food, drink and alcohol

Alcohol may increase drowsiness and may increase the risk of respiratory failure if taken with Suboxone. **Do not take Suboxone together with alcohol.** Do not swallow or consume food or any drink until the tablet is completely dissolved.

Pregnancy and breast-feeding

The risks of using Suboxone in pregnant women are not known. Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will decide if your treatment should be continued with an alternative medicine.

When taken during pregnancy, particularly late pregnancy, medicines like Suboxone may cause drug withdrawal symptoms including problems with breathing in your newborn baby. This may appear several days after birth.

Do not breast-feed whilst taking this medicine, since Suboxone passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Suboxone may cause drowsiness. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative medicines when you take Suboxone. Do not drive, use any tools or machines, or perform dangerous activities until you know how this medicine affects you.

Suboxone contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Suboxone

Your treatment is prescribed and monitored by doctors who are experienced in the treatment of drug dependence.

Your doctor will determine the best dose for you. During your treatment, the doctor may adjust the dose, depending upon your response.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Starting Treatment

The recommended starting dose for adults and adolescents over the age of 15 years is one to two tablets of Suboxone 2 mg/0.5 mg. An additional one to two tablets of the Suboxone 2 mg/0.5 mg may be administered on day 1 depending on your needs.

Clear signs of withdrawal should be evident before taking your first dose of Suboxone. A doctor's assessment of your readiness for treatment will guide the timing of your first Suboxone dose.

- Starting treatment of Suboxone whilst dependent on heroin

If you are dependent upon heroin or a short acting opioid, your first dose of Suboxone should be taken when signs of withdrawal appear, but not less than 6 hours after you last used opioids.

- Starting treatment of Suboxone whilst dependent on methadone

If you have been taking methadone or a long acting opioid, the dose of methadone should ideally be reduced to below 30 mg/day before beginning Suboxone therapy. The first dose of Suboxone should be taken when signs of withdrawal appear, but not less than 24 hours after you last used methadone.

Taking Suboxone

- Take the dose once a day by placing the tablets under the tongue.
- Keep the tablets in place under the tongue until they have **completely dissolved**. This may take 5-10 minutes.
- Do not chew or swallow the tablets, as the medicine will not work and you may get withdrawal symptoms.
- Do not consume any food or drink until the tablets have completely dissolved.

Dosage adjustment and maintenance therapy:

During the days after you start treatment, your doctor may increase the dose of Suboxone you take according to your needs. If you have the impression that the effect of Suboxone is too strong or too weak, talk to your doctor or pharmacist. The maximum daily dose is 24 mg (i.e. equal to three Suboxone 8 mg/2 mg tablets when the patient is stabilised in treatment).

After a time of successful treatment, you may agree with your doctor to reduce the dose gradually to a lower maintenance dose.

Stopping Treatment

Depending on your condition, the dose of Suboxone may continue to be reduced under careful medical supervision, until eventually it may be stopped.

Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

If you take more Suboxone than you should

If you or someone else takes too much of this medicine, you must go or be taken immediately to an emergency centre or hospital for treatment as **overdose** with Suboxone may cause serious and life-threatening breathing problems.

Symptoms of overdose may include feeling sleepy and uncoordinated with slowed reflexes, blurred vision, and/or slurred speech. You may be unable to think clearly, and may breathe much slower than is normal for you.

If you forget to take Suboxone

Tell your doctor as soon as possible if you miss a dose.

If you stop taking Suboxone

Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you. **Stopping treatment suddenly may cause withdrawal symptoms.**

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Suboxone can cause side effects, although not everybody gets them.

Tell your doctor immediately or seek urgent medical attention if you experience uncommon side effects, such as:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, severe hives/nettle rash. These may be signs of a life-threatening allergic reaction.
- feeling sleepy and uncoordinated, have blurred vision, have slurred speech, cannot think well or clearly, or your breathing gets much slower than is normal for you.

Also tell your doctor immediately if you experience uncommon side effects such as:

- severe tiredness, itching with yellowing of skin or eyes. These may be symptoms of liver damage.
- seeing or hearing things that are not there (hallucinations).

Side effects reported with Suboxone
<i>Very common side effects(may affect more than one in 10 people):</i>
Insomnia (inability to sleep), constipation, nausea, sweating, headache, drug withdrawal syndrome
<i>Common side effects (may affect up to 1 in 10 people):</i>
Weight loss, swelling (hands and feet), tiredness, drowsiness, anxiety, nervousness, tingling, depression, decreased sexual drive, increase in muscle tension, abnormal thinking, increased tearing (watering eyes) or other tearing disorder, blurred vision, flushing, increased blood pressure, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach or other stomach discomfort, diarrhoea, abnormal liver function, loss of appetite, flatulence, vomiting, rash, itching, hives, pain, joint pain, muscle pain, leg cramps (muscle spasm), difficulty in getting or keeping an erection, urine abnormality, abdominal pain, back pain, weakness, infection, chills, chest pain, fever, flu-like symptoms, feeling of general discomfort, accidental injury caused by loss of alertness or co-ordination, faintness and dizziness, drop in blood pressure on changing position from sitting or lying down to standing.
<i>Uncommon side effects (may affect up to 1 in 100 people):</i>
Swollen glands (lymph nodes), agitation, tremor, abnormal dream, excessive muscle activity, depersonalization (not feeling like yourself), medicine dependence, amnesia (memory disturbance), loss of interest, exaggerated feeling of well being, convulsion (fits), speech disorder, small pupil size, difficulty urinating, eye inflammation or infection, rapid or slow heart beat, low blood pressure, palpitations, myocardial infarction (heart attack), chest tightness,

shortness of breath, asthma, yawning, pain and sores in mouth, tongue discolouration, acne, skin nodule, hair loss, dry or scaling skin, inflammation of joints, urinary tract infection, abnormal blood tests, blood in urine, abnormal ejaculation, menstrual or vaginal problems, kidney stone, sensitivity to heat or cold, heat stroke, feelings of hostility.
<i>Rare side effects (may affect up to 1 in 1000 people):</i>
Slow or difficult breathing, liver injury with or without jaundice, hallucinations, swelling of face and throat or life threatening allergic reactions.
<i>Not known (frequency can not be estimated from the available data):</i>
Sudden withdrawal syndrome caused by taking Suboxone too soon after use of illicit opioids, drug withdrawal syndrome in newborn. Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems (see Warnings and precautions).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6767836
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Suboxone

This medicinal product does not require any special storage conditions. However, Suboxone can be a target for people who abuse prescription medicine. Keep this medicine in a safe place to protect it from theft.

Keep out of the sight and reach of children and other household members.

Buprenorphine may cause severe possibly fatal respiratory depression in children and non-dependent persons in case of accidental or deliberate ingestion.

Store the blister safely.

Never open the blister in advance.

Do not take this medicine in front of children.

An emergency unit should be contacted immediately in case of accidental ingestion or suspicion of ingestion.

Do not use Suboxone after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other Information

What Suboxone contains

- The active substances are buprenorphine and naloxone.
Each 8 mg/2 mg tablet contains 8 mg buprenorphine (as hydrochloride) and 2 mg naloxone (as hydrochloride dihydrate).
- The other ingredients are lactose monohydrate, mannitol, maize starch, povidone K30, citric acid anhydrous, sodium citrate, magnesium stearate, acesulfame potassium and natural lemon and lime flavour.

What Suboxone looks like and contents of the pack

Suboxone 8 mg/2 mg sublingual tablets are white hexagonal biconvex tablets of 11 mm, embossed with a sword logo on one side and “N8” on the reverse side.

Packed in packs of 7 and 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Manufacturer:

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For any information about this medicine, please contact the Marketing Authorisation Holder:

België/Belgique/Belgien, България, Česká republika, Danmark, Deutschland, Eesti, Ελλάδα, España, France, Ireland, Ísland, Italia, Κύπρος, Latvija, Lietuva, Luxembourg/Luxemburg, Magyarország, Malta, Nederland, Norge, Österreich, Polska, Portugal, România, Slovenija, Slovenská republika, Suomi/Finland, Sverige, United Kingdom.

RB Pharmaceuticals Limited

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Detailed information on this medicine is available on the website of the European Medicines Agency
<http://www.ema.europa.eu/>