

Package leaflet: Information for the user

Suboxone 2 mg/0.5 mg sublingual film

Suboxone 4 mg/1 mg sublingual film

Suboxone 8 mg/2 mg sublingual film

Suboxone 12 mg/3 mg sublingual film

buprenorphine/naloxone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Suboxone is and what it is used for

Suboxone is used to treat **dependence to opioid (narcotic) drugs such as heroin or morphine in patients 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 you need to know before you take Suboxone

Do not take Suboxone:

- if you are **allergic to buprenorphine, naloxone** or any of the other ingredients of this medicine listed in section 6);
- if you have **serious breathing problems**;
- if you have **serious problems with your liver**;
- if you are **intoxicated due to alcohol** or have trembling, sweating, anxiety, confusion, or hallucinations caused by alcohol;
- if you are **taking naltrexone** or **nalmefene** for the treatment of alcohol or opioid dependence.

Warnings and precautions

Talk to your doctor before taking Suboxone if you have:

- asthma or other breathing problems
- problems with your liver such as hepatitis
- low blood pressure
- recently suffered a head injury or brain disease
- a urinary disorder (especially linked to enlarged prostate in men)

- any kidney disease
- thyroid problems
- adrenocortical disorder (e.g. Addison's disease)
- depression or other conditions that are treated with antidepressants. The use of these medicines together with Suboxone can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Suboxone').

Important things to be aware of:

- An emergency unit should be contacted immediately in case of accidental ingestion or suspicion of ingestion.
- **Additional monitoring**
You may be more closely monitored by your doctor if you are over the age of 65. .
- **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 (see section 5). **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 buprenorphine or have taken it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.

This medicine may cause severe, possibly fatal, respiratory depression (reduced ability to breathe) in children and non-dependent people who accidentally or deliberately take it.
- **Dependence**
This medicine can cause dependence.
- **Withdrawal symptoms**
This medicine can cause opioid withdrawal symptoms if you take it too soon after taking opioids. You should leave at least 6 hours after you use a short-acting opioid (e.g. morphine, heroin) or at least 24 hours after you use a long-acting opioid such as methadone.

This medicine can also cause withdrawal symptoms if you stop taking it abruptly. See section 3 'stopping treatment'.
- **Liver damage**
Liver damage has been reported after taking Suboxone, especially when the medicine is misused. This could also be due to viral infections (e.g. chronic hepatitis C), 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 medicine 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. You must tell your doctor that you take this medicine.

Children and adolescents

Do not give this medicine to **children under the age of 15**. If you are between 15 and 18 years old your doctor may monitor you more closely during treatment, because of the lack of data in this age group.

Other medicines and Suboxone

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may increase the side effects of Suboxone, and these can be serious. 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, or alprazolam. Concomitant use of Suboxone and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe Suboxone together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- **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 may 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 painkillers and cough suppressants.
 - Antidepressants (used to treat depression) such as isocarboxazid, phenelzine, selegiline, 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.
- **Anti-depressants** such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Suboxone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles, that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- Clonidine (used to treat high blood pressure) may extend the effects of this medicine.
- Antiretrovirals (used to treat HIV) 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 and nalmefene (medicines used to treat addictive disorders) may prevent the therapeutic effects of Suboxone. They should not be taken at the same time as Suboxone treatment because you may experience a sudden onset of prolonged and intense withdrawal.

Suboxone with food, drink and alcohol

Do not have alcohol whilst being treated with this medicine. Alcohol may increase drowsiness and may increase the risk of respiratory failure if taken with Suboxone. Do not swallow or consume food or any drink until the film is completely dissolved.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. The risks of using Suboxone in pregnant women are not known. 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, as buprenorphine passes into breast milk.

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

Driving and using machines

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

Suboxone contains maltitol, sunset yellow (E110) and sodium.

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

Suboxone contains sunset yellow (E110), which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per film, that is to say essentially 'sodium free'.

3. How to take Suboxone

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

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 to treatment.

Starting treatment

The recommended starting dose for adults and adolescents over the age of 15 years is usually two Suboxone 2 mg/0.5 mg sublingual films, or one Suboxone 4 mg/1 mg sublingual film.

This dose may be repeated up to twice on day 1 depending on your needs.

You should be aware of the clear signs of withdrawal before taking your first dose of Suboxone. Your doctor will tell you when to take your first dose.

- Starting treatment of Suboxone whilst **dependent on heroin**

If you are dependent upon heroin or a short-acting opioid, your first dose should be taken when signs of withdrawal appear, **at least 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, and at **least 24 hours after you last used methadone.**

Dose 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 think that the effect of Suboxone is too strong or too weak, talk to your doctor or pharmacist. **The maximum daily dose is 24 mg buprenorphine.**

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

Taking Suboxone

- Take the dose once a day, at approximately the same time.
- It is advisable to moisten your mouth before taking the film.
- Place the sublingual film under the tongue (sublingual use) or on the inside of the cheek (buccal use) as advised by your doctor. Ensure the films do not overlap.
- Keep the films in place under the tongue, or inside of the cheek, until they have **completely dissolved.**
- **Do not chew or swallow** the film, as the medicine will not work, and you may get withdrawal symptoms.
- Do not consume any food or drink until the film has completely dissolved.
- Do not split the film or subdivide into smaller doses.

How to remove the film from the sachet

Each Suboxone film comes in a sealed child-resistant sachet. Do not open the sachet until you are ready to use it.

To open the sachet, find the dotted line that runs along the top edge of the sachet and fold the edge of the sachet along the dotted line (see Figure 1).



Figure 1

- Folding the sachet along the dotted line exposes a slit through the folded edge of the sachet that can then be torn in the direction of the arrow.
- Alternatively, the sachet may be cut with scissors along the arrow (see Figure 2).



Figure 2

If the sachet is damaged, discard the film.

How to place a film under your tongue (sublingual use):

Drink water to moisten your mouth first. This helps the film dissolve more easily. Then, hold a film between two fingers by the outside edges, and place the film under your tongue, close to the base either to the left or right (see Figure 3).



Figure 3

If your doctor tells you to take two films at a time, place the second film under your tongue on the opposite side. Ensure the films do not overlap

If your doctor tells you to take a third film, place it under your tongue on either side after the first two films have dissolved.

How to place a film on the inside of your cheek (buccal use):

Drink water to moisten your mouth. Hold the film between two fingers by the outside edges and place one film on the inside of your right or left cheek (see Figure 4).

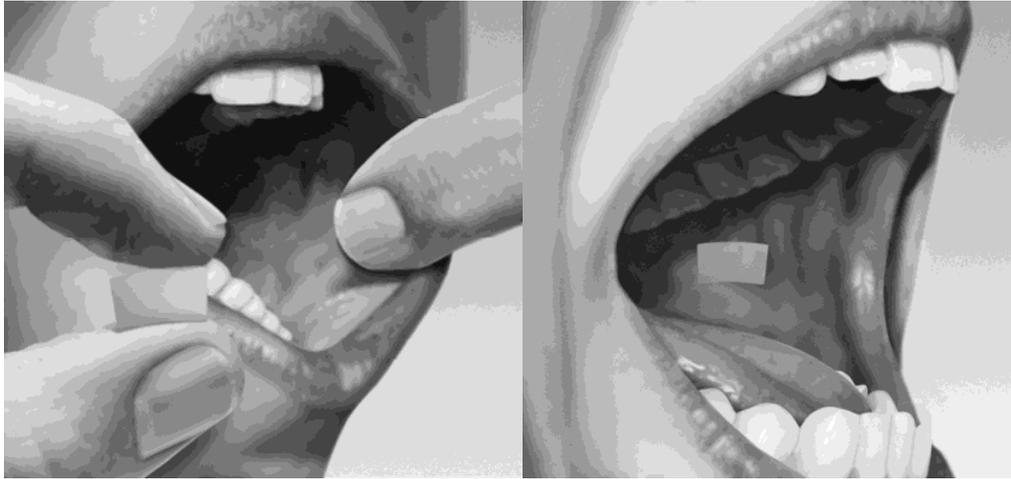


Figure 4

If your doctor tells you to take two films at a time, place the other film on the inside of the opposite cheek: and this will ensure that the films do not overlap. If your doctor tells you to take a third film, place it on the inside of your right or left cheek after the first two films have dissolved.

If you take more Suboxone than you should

Seek urgent medical attention if you or someone else takes too much of this medicine. 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

Stopping treatment suddenly may cause withdrawal symptoms. 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately or seek urgent medical attention if you experience 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.
- 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).

Very common side effects (may affect more than one in 10 people):
Insomnia (inability to sleep), constipation, nausea, excessive sweating, headache, drug withdrawal syndrome.
Common side effects (may affect up to 1 in 10 people):
Weight loss, swelling of the hands and feet, drowsiness, anxiety, nervousness, tingling, depression, decreased sexual drive, increase in muscle tension, abnormal thinking, increased tearing (watering eyes) or other tearing disorders, flushing, increased blood pressure, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach or other stomach discomfort, diarrhoea, mouth redness, abnormal liver function, 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, dizziness.
Uncommon side effects (may affect up to 1 in 100 people):
Swollen glands (lymph nodes), agitation, tremor, abnormal dreams, excessive muscle activity, depersonalisation (not feeling like yourself), medicine dependence, amnesia (memory disturbance), loss of interest, disturbance in attention, exaggerated feeling of wellbeing, convulsion (fits), speech disorder, small pupil size, difficulty urinating, blurred vision, eye inflammation or infection, rapid or slow heartbeat, low blood pressure, palpitations, heart attack, chest tightness, shortness of breath, asthma, yawning, mouth problems (sores, blisters, numbness, tingling, swelling, or pain), tongue discolouration or pain, 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, protein in your urine, painful or difficult urination, sensitivity to heat or cold, heat stroke, allergic reaction, loss of appetite, feelings of hostility, intoxication.
Not known (frequency cannot be estimated from the available data):
Sudden withdrawal syndrome caused by taking Suboxone too soon after use of illicit opioids, drug withdrawal syndrome in new-born babies, slow or difficult breathing, liver injury with or without jaundice, hallucinations, swelling of face and throat or life-threatening allergic reactions, drop in blood pressure on changing position from sitting or lying down to standing, causing dizziness, irritation or inflammation inside the mouth, including under the tongue.

Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems (see Warnings and precautions).

Reporting of side effects

If you get any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Suboxone

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

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

Store below 25 °C.

Suboxone can be a target for people who abuse prescription medicine. Keep this medicine in a safe place to protect it from theft.

Store the sachet safely.

Never open the sachet in advance.

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

6. Contents of the pack and other information

What Suboxone contains

- The active substances are buprenorphine and naloxone.
Each 2 mg/0.5 mg film contains 2 mg buprenorphine (as hydrochloride) and 0.5 mg naloxone (as hydrochloride dihydrate).
Each 4 mg/1 mg film contains 4 mg buprenorphine (as hydrochloride) and 1 mg naloxone (as hydrochloride dihydrate).
Each 8 mg/2 mg film contains 8 mg buprenorphine (as hydrochloride) and 2 mg naloxone (as hydrochloride dihydrate).
Each 12 mg/3 mg film contains 12 mg buprenorphine (as hydrochloride) and 3 mg naloxone (as hydrochloride dihydrate).
- The other ingredients are macrogol, maltitol liquid, natural lime flavour, hypromellose, citric acid, acesulfame potassium, sodium citrate, sunset yellow (E110) and white ink.

What Suboxone looks like and contents of the pack

Suboxone 2 mg/0.5 mg sublingual films are orange rectangular films of nominal dimensions 22.0 mm × 12.8 mm, with 'N2' imprinted in white ink.

Suboxone 4 mg/1 mg sublingual films are orange rectangular films of nominal dimensions 22.0 mm × 25.6 mm, with 'N4' imprinted in white ink.

Suboxone 8 mg/2 mg sublingual films are orange rectangular films of nominal dimensions 22.0 mm × 12.8 mm, with 'N8' imprinted in white ink.

Suboxone 12 mg/3 mg sublingual films are orange rectangular films of nominal dimensions 22.0 mm × 19.2 mm, with 'N12' imprinted in white ink.

The films are packed in individual sachets.

Pack sizes: cartons containing 7 × 1, 14 × 1 and 28 × 1 films.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Indivior UK Limited
The Chapleo Building
Henry Boot Way
Priory Park
Hull
HU4 7DY
United Kingdom

Manufacturer

Indivior Europe Limited
27 Windsor Place
Dublin 2
D02 DK44
Ireland

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

Indivior UK Limited
Tel: 0808 234 9243

e-mail: PatientSafetyRoW@indivior.com

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