

SUBOXONE® FILM

Buprenorphine Hydrochloride + Naloxone Hydrochloride Dihydrate

Consumer Medicine Information

What is in this leaflet

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

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

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

Keep this leaflet.

You may need to read it again.

What SUBOXONE FILM is used for

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

SUBOXONE FILM contain the active ingredients buprenorphine hydrochloride and naloxone hydrochloride dihydrate.

Buprenorphine acts as a substitute for opioids and it helps withdrawal from opioids over a period of time. When taken sublingually (under the tongue) or buccally (inside the cheek) as prescribed, naloxone has no effect, as it is very poorly absorbed. However, if SUBOXONE FILM is injected, naloxone will act to block the effects of other opioids like heroin, methadone, morphine, oxycodone or codeine, leading to bad withdrawal symptoms. Therefore, naloxone is included in SUBOXONE FILM to discourage misuse by injection, as it can cause very bad withdrawal symptoms.

SUBOXONE FILM should be used exactly as prescribed by your doctor.

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

Before you take SUBOXONE FILM

SUBOXONE FILM is not suitable for everyone.

When you must not take SUBOXONE FILM

- 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. tranquilisers, sedative/hypnotics, narcotic analgesics, anti-anxiety medicines, antipsychotics), alcohol or have delirium tremens (the 'shakes' and hallucinations).
- Do not take SUBOXONE FILM if the package is torn, shows signs of tampering or the films do not look quite right.

Before you start to use SUBOXONE FILM

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 FILM.

- 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
- 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 FILM.

Whilst you are being treated with SUBOXONE FILM, do not use benzodiazepines unless they have been prescribed by your doctor.

SUBOXONE FILM may cause fatal respiratory failure if children accidentally ingest it.

Keep this medicine out of reach and sight of children.

As SUBOXONE FILM 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 or buccally, SUBOXONE FILM 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 FILM 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 FILM is not intended for occasional use and should be taken only as prescribed.

SUBOXONE FILM 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 FILM 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 FILM.

A number of medicines may alter the effects of SUBOXONE FILM. 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
- antipsychotic medicines
- other opioid 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 FILM.

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 FILM. You should not use benzodiazepines whilst you are taking SUBOXONE FILM unless they are prescribed by your doctor.

How to Take SUBOXONE FILM

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

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

Before touching the film, make sure your hands are dry. SUBOXONE FILM should be held between 2 fingers by the outside edges of the film. The films are taken sublingually and/or buccally. This means that you place the film under your tongue and/or inside

either cheek and allow it to dissolve, which may take between 4 and 8 minutes. This is the only way the films should be taken. If you need to take two films, place them on opposite sides under your tongue or inside your cheeks and try not to have them overlap. If you are taking more than 2 films, place the next films under your tongue or inside your cheeks after the first two have dissolved.

Do not swallow or consume food or drink until the films are completely dissolved. The films will not work if you chew or swallow them whole. They are not designed to be split or broken.

Do not inject SUBOXONE FILM; 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 FILM is only for adults and children over the age of 16 years. Your doctor will tell you how much SUBOXONE FILM to take and you should always follow medical advice.

Each SUBOXONE FILM contains buprenorphine and naloxone. SUBOXONE FILM 2/0.5 containing 2mg buprenorphine and 0.5mg naloxone is referred to as 'the 2mg film', SUBOXONE FILM 4/1 containing 4mg buprenorphine and 1mg naloxone is referred to as 'the 4mg film', SUBOXONE FILM 8/2 containing 8mg buprenorphine and 2mg naloxone is referred to as 'the 8mg film' and SUBOXONE FILM 12/3 containing 12mg buprenorphine and 3mg naloxone is referred to as 'the 12mg film'.

On the first day the usual starting dose is 4-8 mg SUBOXONE FILM 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 FILM 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 FILM, your doctor will probably reduce your dose of methadone to the minimum daily dose that you can tolerate. The first dose of SUBOXONE FILM should preferably be taken when the first signs of craving appear and at least 24 hours after your last dose of methadone.

SUBOXONE FILM 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 FILM up 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 films, as this may cause withdrawal symptoms.

If you miss a dose of SUBOXONE FILM

If you miss a dose of SUBOXONE FILM, 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 FILM.

If you take too much SUBOXONE FILM (overdose)

If you think that you or anyone else may have taken too much SUBOXONE FILM, 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 FILM, 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 FILM 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 FILM 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.
- pain
- headache

Other side effects which have occurred are:

- headache, migraine
- sleepiness, dizziness
- abnormal vision
- depression, abnormal thinking
- reduced sex drive
- chest pain
- nausea, vomiting, constipation, wind, indigestion, decreased weight
- hives
- flushing, swelling of the legs and arms
- difficulty urinating
- rash and itching
- toothache
- respiratory infection
- redness in mouth, inflammation of the tongue
- sinus problems

- dizziness or fainting when standing up
- If you think you are experiencing any of the above 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 with symptoms of severe fatigue, no appetite, yellow skin or eyes, light coloured bowel motions or dark coloured urine.

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 FILM

If you stop taking SUBOXONE FILM and restart your opioid use, you are at risk of being more sensitive to opioids, which could be dangerous. You should talk to your doctor if you commence using opioids again.

Storage

SUBOXONE FILM contains a narcotic that can be a target for people who abuse prescription medicines or street drugs. Therefore, keep your medications in a safe place to protect them from theft. Never give them to anyone else.

The films should be stored below 25°C in the original package. SUBOXONE FILM 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 FILM after the expiry date that is shown on the pack.

Product Description

What SUBOXONE FILM Looks Like

SUBOXONE FILM is an orange, rectangular soluble film. A logo is printed on each film to indicate the dosage strength: "N2" for the 2mg, "N4" for the 4mg, "N8" for the 8mg and "N12" for the 12mg.

Ingredients:

Each SUBOXONE FILM 2/0.5 contains 2mg buprenorphine (as hydrochloride) + 0.5mg naloxone (as hydrochloride dihydrate) as active ingredients. Each SUBOXONE FILM 4/1 contains 4mg buprenorphine (as hydrochloride) + 1mg naloxone (as hydrochloride dihydrate) as active ingredients. Each SUBOXONE FILM 8/2 contains 8mg buprenorphine (as hydrochloride) + 2mg naloxone (as hydrochloride dihydrate) as active ingredients. Each SUBOXONE FILM 12/3 contains 12mg buprenorphine (as hydrochloride) + 3mg naloxone (as hydrochloride dihydrate) as active ingredients.

SUBOXONE FILM also contains the following inactive ingredients: acesulfame potassium, citric acid, maltitol, hypromellose, polyethylene oxide, sodium citrate, Natural Lime Flavour 3000180,

Sunset Yellow FCF and OPACODE WB
monogramming ink NS-78-18007 White.

Each pack of SUBOXONE FILM 2/0.5 is
labelled with AUST R 163443

Each pack of SUBOXONE FILM 4/1 is
labelled with AUST R 211117*

Each pack of SUBOXONE FILM 8/2 is
labelled with AUST R 163444

Each pack of SUBOXONE FILM 12/3 is
labelled with AUST R 211120*

*Not currently supplied.

Sponsor:

Indivior Pty Ltd
78 Waterloo Road
Macquarie Park NSW 2113
Australia

For adverse event reporting please contact:

Indivior Pty Ltd
+800-270-81901
PatientSafetyRoW@indivior.com

Date of Preparation:

November 2019