SUBOXONE® FILM

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using SUBOXONE FILM?

SUBOXONE FILM contains two active ingredients buprenorphine hydrochloride and naloxone hydrochloride dihydrate. SUBOXONE FILM is used as part of medical, social and psychological treatment program for patients dependent on opioids.

For more information, see Section 1. Why am I using SUBOXONE FILM? in the full CMI.

2. What should I know before I use SUBOXONE FILM?

Do not use if you have ever had an allergic reaction to SUBOXONE FILM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use SUBOXONE FILM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SUBOXONE FILM and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use SUBOXONE FILM?

- SUBOXONE FILM should be used exactly as prescribed by your doctor or healthcare professional.
- The usual starting dose of SUBOXONE FILM is 4 - 8 mg with an additional 4 mg depending on your needs as determined by your treating doctor. The subsequent dosing will be selected by your healthcare professional based on clinical assessment of your condition.

More instructions can be found in Section 4. How do I use SUBOXONE FILM? in the full CMI.

5. What should I know while using SUBOXONE FILM?

Things you should do	• Remind any doctor, dentist, nurse or pharmacist you visit that you are using SUBOXONE FILM. • Tell your family or friends that, in the event of emergency, they should inform the treating healthcare provider or Emergency Room staff that you are being treated with SUBOXONE FILM.
Things you should not do	• Do not inject this medicine. • Do not swallow or consume food or drink until the films are completely dissolved. • Do not stop using this medicine suddenly.
Driving or using machines	• SUBOXONE FILM may affect your alertness and ability to drive and operate machinery. Be careful driving or

	operating machinery until you know how SUBOXONE FILM affects you.
Drinking alcohol	• Do not drink alcohol or take medicines that contain alcohol whilst being treated with SUBOXONE FILM. Alcohol and some medicines may increase the sedative effects of SUBOXONE FILM.
Looking after your medicine	• Keep the films in a dry place where temperature stays below 25°C. Store this medicine securely, where other people cannot access it. It may harm people who take this medicine by accident, or intentionally.

For more information, see Section 5. What should I know while using SUBOXONE FILM? in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNINGS:

Hazardous and harmful use

Although SUBOXONE FILM 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 FILM.

Life threatening respiratory depression

Serious, life-threatening respiratory depression may occur with the use of SUBOXONE FILM. 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 FILM with anti-anxiety medicines, sedatives, antihistamines, some antidepressants, antipsychotics, cannabis and alcohol may result in profound sedation, respiratory depression, coma and death.

SUBOXONE FILM

Active ingredient(s): *buprenorphine hydrochloride and naloxone hydrochloride dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SUBOXONE FILM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SUBOXONE FILM.**

Where to find information in this leaflet:

1. Why am I using SUBOXONE FILM?
2. What should I know before I use SUBOXONE FILM?
3. What if I am taking other medicines?
4. How do I use SUBOXONE FILM?
5. What should I know while using SUBOXONE FILM?
6. Are there any side effects?
7. Product details

1. Why am I using SUBOXONE FILM?

SUBOXONE FILM contains two 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 is used as part of a medical, social and psychological treatment program for patients dependent on opioids.

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

2. What should I know before I use SUBOXONE FILM?

Warnings

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.

Opioids can cause

- **sleep apnoea (stopping breathing from time to time while sleeping) which can lead to low levels of oxygen in the blood. Tell your doctor if you have a history of sleep apnoea or if anyone notices you stop breathing from time to time whilst sleeping.**
- **a decreased level of hormones in the blood caused by a problem with the adrenal glands. The effects of these hormone changes may include nausea, vomiting, loss of appetite, feeling very tired and weak, feeling dizzy, or low blood pressure.**

- **an increased level of the hormone ‘prolactin’ and decreased level of sex hormones in the blood.**

Tell your doctor if you notice any of these symptoms. You may need blood tests, and your doctor may tell you to stop using SUBOXONE FILM.

Do not use SUBOXONE FILM if:

- you are allergic to buprenorphine or to naloxone or to of the ingredients listed at the end of this leaflet.
- you are taking benzodiazepines unless they have been prescribed by your doctor.
- always check the ingredients to make sure you can use this medicine.
- you have serious problems with your liver, or if your doctor detects the development of a serious liver problem during treatment.
- you are under the age of 16 years.
- you have serious breathing problems.
- you are intoxicated due to CNS depressant medicines (e.g. tranquilisers, sedative/hypnotics, narcotic pain killers, anti-anxiety or antipsychotic medicines), alcohol or have delirium tremens (the ‘shakes’ and hallucinations).
- the package is torn, shows signs of tampering or the films do not look quite right.

Check with your doctor if you:

- have any other medical conditions such as 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,

- have head injuries or have a condition where you have increased pressure within your head
- have problems related to the biliary tract
- have a history of seizures or if you have severe mental problems or hallucinations (seeing or hearing things that are not really there).
- take any medicines for any other condition.

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.

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.

SUBOXONE FILM can cause withdrawal symptoms (dependence) 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 morphine or heroin) or less than 24 hours after a long-acting opioid (such as methadone) when taken sublingually or buccally

- stop using the medicine too quickly. Withdrawal symptoms may be delayed in some cases.

SUBOXONE FILM may cause

- fatal respiratory failure in children who accidentally ingest it.
- 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.
- your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down.
- withdrawal symptoms if taken while still under the influence of another opioid.

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

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use of SUBOXONE FILM or other opioids by the mother during pregnancy may result in withdrawal symptoms in the baby following birth, this is called Neonatal Abstinence Syndrome. Neonatal Abstinence Syndrome is a condition that includes disturbances to a newborn baby's nervous, gastro-intestinal and breathing systems. Not all babies who are exposed to SUBOXONE FILM in this way will have withdrawal symptoms. Talk to your doctor if you become pregnant or plan to become pregnant during treatment with SUBOXONE FILM. Your doctor will help you consider the risks and benefits of continued treatment and plan for monitoring your baby following birth. Due to the long duration of buprenorphine effect, your baby will be monitored for several days at the end of pregnancy for effects on breathing and for withdrawal symptoms.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with SUBOXONE FILM and affect how it works.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- medicines containing alcohol
- certain medicines for treating HIV/AIDS
- certain medicines for treating fungal and bacterial infections
- strong painkillers
- 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
- antipsychotic medicines
- naltrexone
- other opioid medicines.

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

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, alcohol or other opioids at the same time as SUBOXONE FILM. You should not use benzodiazepines (medicines used to treat anxiety or sleep disorders) whilst you are taking SUBOXONE FILM unless they are prescribed by your doctor.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SUBOXONE FILM.

4. How do I use SUBOXONE FILM?

How much to use

- Each SUBOXONE FILM contains buprenorphine and naloxone and is available in four different strengths:
  - SUBOXONE FILM 2/0.5 containing 2 mg buprenorphine and 0.5 mg naloxone, it is referred to as 'the 2 mg film'
  - SUBOXONE FILM 4/1* containing 4 mg buprenorphine and 1 mg naloxone, it is referred to as 'the 4m g film'
  - SUBOXONE FILM 8/2 containing 8 mg buprenorphine and 2 mg naloxone, it is referred to as 'the 8 mg film' and

- SUBOXONE FILM 12/3* containing 12 mg buprenorphine and 3 mg naloxone, it is referred to as 'the 12 mg film'.

*Not currently supplied.

- **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 at least 24 hours after your last dose of methadone or when the first signs of craving appear.

How to use SUBOXONE FILM

- **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.

- During your treatment, your doctor may increase your dose of SUBOXONE FILM up to a maximum daily dose of 32 mg, 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 swallow, consume food or drink until the films are completely dissolved. The films will not work if you chew of swallow them whole. They are not designed to be split or broken.

DO NOT inject SUBOXONE FILM. Patients have died from injecting this medicine. Additionally, when injecting SUBOXONE FILM and also taking benzodiazepines (medicines used to treat anxiety or sleeping problems), people were even more likely to die.

If you forget to use SUBOXONE FILM

If you miss your dose of SUBOXONE FILM, take it as soon as you remember. If you are unsure consult your doctor, nurse or pharmacist.

If you use too much SUBOXONE FILM

If you think that you have used too much SUBOXONE FILM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose with SUBOXONE FILM may include:

- severe drowsiness, dizziness or difficulty thinking
- severe drop in blood pressure
- severe difficulty breathing.

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while using SUBOXONE FILM?

Things you should do

If you are about to start on any new medicine, remind your doctor, nurse and pharmacist who treat you that you are using or will be starting SUBOXONE FILM.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using SUBOXONE FILM.

It may affect other medicines used during surgery.

Keep all of your doctor/nurse/pharmacist's appointments so that your progress can be checked.

Call your doctor straight away if you:

- experience allergic reactions such as swelling of the face, lips, mouth or throat, or severe difficulty in breathing, or
- experience severe liver problems such as intense fatigue, no appetite, your skin and eyes look yellow,

or you have light coloured bowel motions or dark coloured urine.

- experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.
- have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.

Remind any doctor, dentist, nurse or pharmacist you visit that you are using SUBOXONE FILM.

Things you should not do

- **Do not inject SUBOXONE FILM. Patients have died from injecting this medicine.**
- **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 stop using this medicine suddenly,** as this may cause withdrawal symptoms.
- Do not take your medicine to treat any condition other than the one prescribed for by your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you. It may harm them.

Things to be careful of

- 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.
- if you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- if you stop using SUBOXONE FILM and if you start using opioids again, your sensitivity to opioids may change which could be dangerous. You should talk to your doctor before you start using opioids again.
- 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

In the event of an emergency

- It is important that your family members or friends tell hospital or ambulance staff that you are dependent on opioids (narcotics) and are being treated with SUBOXONE FILM.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SUBOXONE FILM affects you.

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.

Drinking alcohol

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

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep the films in a dry place where the temperature stays below 25°C in the original package.
- Store this medicine securely, where other people cannot access it. It may harm people who take this medicine by accident, or intentionally when it has not been prescribed for them.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Breathing-related: • sinus problems • respiratory infection **Sleep-related:** • difficulty sleeping, anxiety, nervousness, malaise, fatigue **Pain-related effects:** • pain in abdomen, back, joints and muscles, leg cramps, muscle weakness • headache, migraine • chest pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
Gastrointestinal-related: • upset stomach and diarrhoea • nausea, vomiting, constipation, wind and indigestion **Flu-like symptoms:** • chills, fever, sore throat, coughing, runny nose, watering eyes and sweating **Other:** • depression, abnormal thinking • sleepiness, dizziness • dizziness or fainting, when standing up • flushing, swelling of the legs and arms • hives • rash and itching • redness in mouth, inflammation of the tongue • toothache • abnormal vision • low sex drive	

Less serious side effects	What to do
• difficulty urinating • urinary tract infection • hormone disorders	

Serious side effects

Serious side effects	What to do
Allergy-related: • life-threatening allergic reaction *Symptoms may include:* • severe difficulty breathing • swelling of the face, lips, mouth or throat **Liver-related:** • severe fatigue • you have no appetite • your skin and eyes look yellow • you have light coloured bowel motions or dark coloured urine	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

For adverse event reporting please contact:

Indivior Pty Ltd

Tel: +800-270-81901

PatientSafetyRoW@indivior.com

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SUBOXONE FILM contains

Active ingredient **(main ingredients)**	buprenorphine hydrochloride and naloxone hydrochloride dihydrate
Other ingredients **(inactive ingredients)**	acesulfame potassium citric acid maltitol hypromellose polyethylene oxide sodium citrate Natural Lime Flavour 3000180 Sunset Yellow FCF OPACODE WB monogramming sodium citrate dihydrate
Potential allergens	None Known

Do not take this medicine if you are allergic to any of these ingredients.

What SUBOXONE FILM looks like

SUBOXONE FILM is an orange, rectangular soluble film and is available in the following presentations:

- SUBOXONE FILM 2/0.5 contains 2 mg of buprenorphine (as hydrochloride) + 0.5 mg of naloxone (as hydrochloride dihydrate) AUST R 163443).
- SUBOXONE FILM 4/1 contains 4 mg of buprenorphine (as hydrochloride) + 1 mg of naloxone (as hydrochloride dihydrate) (AUST R 211117). *
- SUBOXONE FILM 8/2 contains 8 mg of buprenorphine (as hydrochloride) + 2 mg of naloxone (as hydrochloride dihydrate) (AUST R 163444).
- SUBOXONE FILM 12/3 contains 12 mg of buprenorphine (as hydrochloride) + 3 mg of naloxone (as hydrochloride dihydrate) (AUST R 211120). *

*Not currently supplied.

A logo is printed on each film in white ink to indicate the dosage strength: "N2" for the 2 mg, "N4" for the 4 mg, "N8" for the 8 mg and "N12" for the 12 mg. SUBOXONE FILM is individually packed and supplied in a pack containing 28 sachets.

Who distributes SUBOXONE FILM

SUBOXONE FILM is distributed in Australia by:

Indivior Pty Ltd

78 Waterloo Road

Macquarie Park NSW 2113

Australia

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