

A Guide to Treatment



A Guide to Treatment

Acknowledgements

This booklet was prepared by:

Dr Adrian Dunlop, Turning Point Alcohol and Drug Centre Jay Jordens, Turning Point Alcohol and Drug Centre

With contributions from:

Dr Nick Lintzeris, Senior Lecturer and Consultant in Addiction Medicine, National Addiction Centre, Institute of Psychiatry, King's College London and South London and Maudsley Trust

Annie Madden and Nicky Bath, AIVL, Australian Injecting & Illicit Drug Users League Susan McGuckin and Gideon Warhaft, NUAA, NSW Users and AIDS Association Sarah Lord, VIVAIDS, Victorian Drug User Group Telea Slavin, Reckitt Benckiser

Information provided by the following people has also been important in compiling this guide:

Associate Professor James Bell, The Langton Centre
Mark Johnston and Peter Muhleisen, Turning Point Alcohol and Drug Centre
Dr Adam Winstock, SSWAHS, Sydney South West Area Health Service

Some information in this booklet has been adapted from Subutex: A Guide to Treatment. We gratefully acknowledge the authors of that booklet and those who contributed information as part of that project.

This booklet was produced with financial support from Reckitt Benckiser, 44 Wharf Rd, West Ryde, NSW, 2114.

Subutex[®], Suboxone[®] and Suboxone[®] Sublingual Film are registered trademarks of Reckitt Benckiser.

Created November 2005 Updated May 2011

© Turning Point Alcohol and Drug Centre 2005

Dear Reader

The Australian Injecting & Illicit Drug Users League (AIVL) is the national organisation representing State and Territory drug user organisations and issues of national significance for people who use or have used illicit drugs. AIVL has been actively involved in developing this booklet, to help drug users make decisions about going on Suboxone Film treatment. We have worked hard to make sure that this booklet covers the issues that are important to you when making a decision about treatment. This booklet may also be helpful for your friends and family members who may want a better understanding of Suboxone Film treatment.

Everybody's circumstances are different, and this booklet is not meant to take the place of you talking to a health worker about your treatment options and particular needs. You may have questions or issues not covered in this booklet. If you have any questions or concerns, please talk to your doctor, pharmacist or counsellor, local drug user organisation, or to others who may have had some experience with Suboxone Film.

AIVL is committed to ensuring that you have the information you need to make an informed decision about your treatment and we hope that you find this booklet useful. AIVL hopes that as many users as possible access this resource, so pass it on to your friends. Most of all, we hope that you find this booklet helpful when making decisions about managing your drug use.

Yours sincerely

Annie Madden

Executive Officer

Australian Injecting & Illicit Drug Users League (AIVL)

Contents

Who is this booklet for?	8
About Suboxone Sublingual Film	
What is Suboxone Sublingual Film?	
Buprenorphine	
Naloxone	11
How Suboxone Sublingual Film works in the body	12
Under the tongue	12
Swallowing	12
Injecting	13
Choosing a treatment for opiate dependence	15
Types of treatment	15
Pharmacotherapies (short-term withdrawal, maintenance, antagonist maintenance)	15
Abstinence-based treatment	16
Suboxone Sublingual Film treatment and support options	17
Your treatment team	17
Counselling	17
Peer-based drug user organisations	18
Narcotics Anonymous	19
Other support	19
Costs of Suboxone Sublingual Film treatment	19
Who should not take Suboxone Sublingual Film?	20
Hypersensitivity to buprenorphine	20
Pregnancy and breastfeeding	20
Depressants and sedatives	21
Other health issues	21
Hepatitis and liver problems	21

Suboxone Sublingual Film treatment	2
Starting up	2
What dose do I take?	2
Can I use other drugs, too?	22
How do I take Suboxone Sublingual Film?	2
What are the side effects?	2
What is 'precipitated withdrawal'?	20
Will I be urine tested?	2
Transferring from Subutex or Suboxone Tablets to Suboxone Sublingual Film	2
Transferring from methadone to Suboxone Sublingual Film	2
Maintenance	28
What's the point of the maintenance stage?	28
How long is the maintenance stage?	2
What are the dispensing arrangements?	2
What dose will I take?	3
Why do I need a routine?	3
What if I miss a dose?	3
Transferring to other maintenance treatments	3
Coming off maintenance treatment	3
Problems and complaints	3
Useful contacts	રા

Who is this booklet for?

This booklet is for people who are dependent on opiates (such as heroin or morphine) and who are considering treatment. It is also for partners, family and friends of people who are opiate dependent and others who may wish to support them in treatment.

'Being dependent' means:

- using opiates more regularly than you want to, or in larger amounts than you want to, or in ways that have become a problem in your life
- not being able to stop using opiates when you want to.

This booklet is about a new medication called Suboxone Sublingual Film (buprenorphine/naloxone). It explains what Suboxone Film is, how it works, and how you can use it for treatment.

Like other maintenance medications, such as Subutex, Suboxone Tablets and methadone, Suboxone Film can be taken as a medium or long-term medication for people who want to reduce or stop using heroin or other opiates.

Suboxone Film treatment is provided by a range of health professionals. A supportive treatment team (usually a doctor and a pharmacist; may also include a drug and alcohol worker) is an essential part of any good treatment program. Support groups, family members and friends can also help you as you go through treatment. Printed information (like this booklet) does not replace the need for good professional advice and a good relationship with your doctor.

If you are already having treatment for opiate dependence (such as methadone or buprenorphine treatment) or thinking about treatment, drug user organisations can provide information about the full range of treatments. There are contact details for these organisations at the end of this booklet.

About Suboxone Sublingual Film

What is Suboxone Sublingual Film?

Suboxone Sublingual Film is the brand name for a new medication for treating people who are dependent on heroin or other opiates (such as morphine). Suboxone Film is an orange rectangular soluble film that you dissolve under your tongue. They have a lime flavour.

Fach Suboxone Film contains:

- buprenorphine (also known as Subutex®), plus
- naloxone (also known as Narcan®).

Each Suboxone Film is four parts buprenorphine to one part naloxone. Suboxone Film comes in two strengths:

- ▶ 2 mg buprenorphine / 0.5 mg naloxone
- ▶ 8 mg buprenorphine / 2 mg naloxone.

Suboxone Tablets were developed in the US in the 1990's as a treatment for opiate dependence. Suboxone Film is a new technology recently developed to improve the dosing experience. Because it contains naloxone, which causes severe withdrawal if it is injected, Suboxone Film is very unattractive to inject. This means Suboxone Film is a safe take away medication for treating opiate dependence. It also means a more normal life for people who are heroin or opiate dependent.

Suboxone Tablets were first made available in the US in 2003 and Suboxone Film in 2010. Since then, over 2 million people in the US have been prescribed Suboxone Tablets or Suboxone Film. In Australia, the Therapeutic Goods Administration registered Suboxone Tablets in 2005 and Suboxone Film in 2011 for the treatment of opiate dependence.

Buprenorphine

Buprenorphine is an opiate. Its full description is a 'partial opiate agonist'. Opiate agonists bind to opiate receptors in nerve cells in the brain and have an opiate-like effect. They are used in treatment for opiate dependence because they hold you and stop you hanging out, without using heroin or other opiates.

There are full and partial opiate agonists. Methadone is a full opiate agonist. Buprenorphine is a partial opiate agonist; this means that it produces only a partial effect when it binds to opiate receptors.

The way different opiate drugs work can be understood using the following example. Receptors are like a lock to a door — only the right key will open the lock, and only opiate-like drugs 'fit' opiate receptors. Opiate effects happen after the door has been opened.

► Full opiate agonists (e.g. heroin, morphine, methadone) — the key fits the lock and opens the door wide, producing full opiate effects.



Partial opiate agonists (e.g. Subutex, Suboxone Tablets & Suboxone Film)

the key fits the lock and opens the door,
 but leaves it only partially ajar, producing
 some opiate effects...

In the case of buprenorphine, this means that:

- ▶ high doses of buprenorphine have milder opiate effects than high doses of methadone
- withdrawing from buprenorphine can be milder than withdrawing from heroin or methadone
- buprenorphine on its own is much less likely to cause overdose than heroin or methadone.

10

However, buprenorphine also has many of the effects and side effects of heroin and other opiates. It can:

- prevent or ease heroin/opiate withdrawal
- reduce cravings for heroin/opiates
- relieve pain
- ▶ have side effects (such as constipation, drowsiness, sweating and headaches).

Buprenorphine has been used to treat pain since the 1980s. There has been over 25 years of international research into the use of buprenorphine to treat opiate dependence, and it has been approved in the form of Subutex for this purpose in Australia since 2000.

Subutex, Suboxone Tablets and Suboxone Film all contain buprenorphine. The difference is that Suboxone Tablets and Suboxone Film also contain naloxone (Narcan).

Naloxone

Naloxone is an 'opiate antagonist'. Opiate antagonists block the brain's opiate receptors, thereby blocking the effects of opiates. The key fits the door, but does not open the door at all. There are no opiate effects, and the naloxone stops other opiates from opening the door and kicks other opiates off the receptors. It is short acting — effects last for 15 to 20 minutes only.



Naloxone (Narcan) has been used to treat opioid overdoses since the 1970s.

If you dissolve Suboxone Film under your tongue as directed, the body will not absorb the naloxone and it will not have any effect. The naloxone will not reduce the effects of the buprenorphine in any way, **as long as the medication is not injected**.

If you are opiate dependent (for example, if you have a habit) and you inject naloxone, you will get a severe and sudden withdrawal reaction.

How Suboxone Sublingual Film works in the body

Under the tongue

A Suboxone Film takes from 4 to 8 minutes to dissolve under your tongue. As the Suboxone Film dissolves, the buprenorphine enters the bloodstream and goes to the brain, producing its opiate effects.

You will feel some effects within 30 to 60 minutes, and the full effects after one to four hours. The duration of effects varies according to the dose and the person taking it. In general, the higher the dose, the longer lasting the effects.



Swallowing

Just like Subutex and Suboxone Tablets the Suboxone Film is **less effective** if swallowed, as it passes through your liver. This breaks down most of the buprenorphine before it gets into your bloodstream.

So it is very important to dissolve the Suboxone Film under your tongue, and not chew or swallow it.

Injecting

Suboxone Film should not be injected. If injected, it can cause painful and collapsed veins and blood clots, and increase your risk of infection.

If Suboxone Film is injected intravenously:

- the buprenorphine will be absorbed into your bloodstream, but
- the naloxone will also be absorbed, blocking the effects of the buprenorphine and any other opiates (such as heroin or methadone) that you might have also taken.

Injecting Suboxone Film has a similar effect to injecting naloxone on its own; an opiate dependent person can have a sudden withdrawal reaction (a sudden 'hanging out'). This may include cravings, anxiety, restlessness, nausea, sweating, stomach pains and diarrhoea. The withdrawal reaction would be severe for 30 minutes and then drop away over several hours or longer.

Comparison of Suboxone Sublingual Film effects				
	Suboxone Film taken under the tongue (sublingually) Suboxone Film taken under injected			
Non heroin /opiate user	\odot	\bigcirc		
Heroin/opiate user not in withdrawal				
Heroin/opiate user in withdrawal	\odot			
Buprenorphine user	\odot	<u></u>		

Key: positive opiate effect opiate withdrawal effect unpredictable effect

Choosing a treatment for opiate dependence

The exact level of effects from injecting depends on:

- ▶ the level of opiate dependence (that is, how much the person is using) the more they are using, the more withdrawal they will have
- ▶ the opiate the person usually takes (such as heroin, methadone or buprenorphine)
- ▶ how long it is since they last had opiates, and whether they are already starting to withdraw (that is, whether they are already hanging out).

It is very hard to know how much withdrawal a person who injects Suboxone Film will have. The following table shows you some possible withdrawal reactions.

Effects of Suboxone Sublingual Film if injected		
Example Likely reaction		
A person taking high-dose methadone (such as 80 mg) who injects Suboxone Film the same day.	A very strong withdrawal reaction that goes on for several hours, possibly longer.	
A person taking heroin regularly (has a habit) who used heroin within the last two hours.	Likely to have a strong withdrawal reaction that could go on for several hours.	
A person taking heroin regularly (has a habit) but who hasn't used heroin for over 12 hours, is withdrawing already (hanging out) and injects Suboxone Film.	May have a strong withdrawal reaction that goes on for several hours.	
A person only using heroin occasionally (no habit) who injects Suboxone Film.	No withdrawal effect (because they don't have a habit) and will get some effect from injecting Suboxone Film. The onset of effects may be delayed.	
A person already taking buprenorphine who injects Suboxone Film.	No withdrawal effect and will get some effect from injecting Suboxone Film. The onset of effects may be delayed.	

Types of treatment

There are a number of different types of treatment for opiate dependence. Some involve taking Suboxone Film and some don't. Different treatments suit different people. As well, the best type of treatment for you might change over time as your needs change.

If you do not think that your treatment is working well for you, you should discuss this with your doctor, case worker or drug user organisation (for contact details, see the list of **Drug user organisations** at the end of the booklet).

Pharmacotherapies

Short-term withdrawal (detox) treatment

Withdrawal treatment is most often short term, usually about one week. The treatment involves taking medication to reduce withdrawal symptoms. Withdrawal treatment can happen in an outpatient setting (such as at home) or in a residential setting (such as in a withdrawal unit or a hospital). It usually combines support from services, family members and peers.

Suboxone Film can be used for a short period to reduce the severity of the withdrawal symptoms.

Maintenance treatment (methadone or buprenorphine)

Maintenance treatment involves taking regular medication for several months to several years. This medication is either methadone or buprenorphine (taken as Subutex, Suboxone Tablet or Suboxone Film).

The medication gives enough opiate to prevent withdrawal, and gives you the space to focus on things other than using. It suits people wanting to make long-term changes to their lifestyle and to reduce illicit drug use.

Specialist drug treatment clinics, general practitioners and pharmacies deliver maintenance programs. You must attend these programs regularly. Additional psychological and social support may also be useful while in maintenance treatment.

The main advantage of maintenance treatment is that it has the greatest success rate in reducing heroin/opiate use. This means you greatly reduce the risk of dying from an overdose, and the risk of contracting blood-borne viruses (such as HIV and hepatitis C). The main disadvantages are the cost (if you have to pay pharmacy and medical fees) and the fact that it ties you to a treatment service for a long period.

Antagonist maintenance treatment (such as with naltrexone)

Naltrexone is an opiate antagonist that, when taken daily, blocks the effects of heroin and other opiates. However, many people who start naltrexone as a maintenance treatment stop taking the tablet soon after starting it and many relapse to heroin or other opiates. The safety and effectiveness of naltrexone implants for the treatment of opiate dependence are yet to be established.

Abstinence-based treatment

There are different models of abstinence-based treatment for opiate dependence, including therapeutic communities (residential drug-free programs). Abstinence-based options may be useful at various times during treatment.

16

Suboxone Sublingual Film treatment and support options

Your treatment team

A treatment team aims to bring the different aspects of treatment together to offer you the medication, professional and personal support you need. Your treatment team should include:

- your doctor (who prescribes the Suboxone Film)
- ▶ the pharmacist or drug and alcohol clinic dispensary (that dispenses the Suboxone Film) and may also include:
- > your counsellor, case worker or other health professionals.



For treatment with Suboxone Film to be safe and effective, you must have adequate medical supervision. You will need to regularly see your treating doctor (who is trained to provide Suboxone Film treatment) to review how your treatment is going. During the initial stage of treatment, you may need to see your doctor more often, until your dose is stabilised.

Counselling

Drug and alcohol clinics generally offer their clients one-on-one or group-based counselling. Other support agencies can usually arrange private counselling. These generally charge fees, but some offer people on low incomes special rates that are more affordable.



Talk to your doctor or see the contact information at the back of this book about where to find counselling. For more information, you can also contact your local community health centre or area health service.

17

Supportive counselling

Supportive counselling services can help you with urgent issues (such as where to get legal advice, help with housing or pension benefits).

Drug and alcohol counselling

Drug and alcohol counsellors can help you understand the effects of your drug use, and provide information about how to reduce the harm that can result from drug use. This includes helping you:

- not to overdose
- ▶ not to catch a blood-borne virus (such as hepatitis C or HIV)
- change your pattern of drug use
- manage cravings
- prevent relapse
- avoid situations that might trigger drug use.

Other types of counselling

Psychiatric or psychological counselling can help you address more in-depth issues (such as managing chronic anxiety or depression). Some registered medical practitioners who provide these services bulk bill through Medicare. Others do not.

Peer-based drug user organisations

There are peer-based drug user organisations in all States and Territories of Australia except Tasmania. 'Peer-based' drug user organisations are run by and for people who use or have used illicit drugs. Drug user organisations support individuals to reduce the potential harms associated with illicit drug use and promote and protect the rights of drug users. They provide peer education, support, advocacy, information and referral on all health, social and legal issues for people who use illicit drugs. Your local drug user organisation can also provide you with information and support in relation to Suboxone Film and other drug treatment options.

18

Narcotics Anonymous

Narcotics Anonymous (NA) is a nonprofit, international, community based organisation for recovering addicts active in over sixty countries. Narcotics Anonymous operates as an abstinence-based support network for people who want to stop using all substances. Narcotics Anonymous works on a fellowship model with members learning from one another how to live drug-free and recover from the effects of addiction in their lives. The core of the NA program is the Twelve Steps. These 'steps' are a set of guidelines or approach to recovery. All groups are confidential and anonymous. Narcotics Anonymous support groups can be found in all major cities and most local areas.



66 If you are unhappy with any part of your drug treatment, talk to your treatment team. If you need some help, contact your local drug user organisation.

Other support

It is important to have support during (and after) your treatment. Support may come from family or friends, case workers, community service providers or specialist drug treatment agencies.

The combination of support that is helpful will differ from person to person; seeking support that suits your particular situation can really benefit your treatment experience.

Costs of Suboxone Sublingual Film treatment

Some service providers and clinics charge fees for medical, counselling or dispensing services. Talk to your doctor and pharmacist about the cost of services.

19

Who should not take Suboxone Sublingual Film?

You should not take Suboxone Film if any of the situations listed below apply to you.

Hypersensitivity to buprenorphine

Do not take Suboxone Film if you are hypersensitive to buprenorphine. Hypersensitivity can show up as rashes, hives and itchy skin. Very occasionally, hypersensitivity causes a severe reaction (such as problems breathing due to airway constriction and anaphylactic shock). If you have had any of these reactions when taking Subutex, Suboxone Tablets or Suboxone Film, do not take it again and see your doctor immediately.

Pregnancy and breastfeeding

Women who are pregnant, breastfeeding or planning to become pregnant, and are using heroin or other opiates, should consider methadone treatment.

If you become pregnant while taking Suboxone Film, you can safely transfer to methadone. Methadone has been widely used by pregnant women for over 30 years.

There is not enough research on the use of buprenorphine by pregnant or breastfeeding women to say clearly that it is as safe as methadone. In some situations, naloxone can be dangerous to a baby during pregnancy and immediately after birth. National buprenorphine guidelines permit treatment with Subutex in pregnancy and breastfeeding, provided there is an adequate assessment of the risks and benefits by the woman and the treatment team (including the obstetric care team) and she can provide consent.

If you are pregnant or breastfeeding and want treatment with buprenorphine, you must discuss the risks and benefits with your doctor and your obstetrician.

If you are in your childbearing years, are heterosexually active and do not want to become pregnant, it is important that you use a reliable form of contraception. Your doctor can recommend something for you. Of course, you should always practice 'safe sex' to reduce the risk of sexually transmitted infection (STI).

Depressants and sedatives

It is dangerous to mix Suboxone Film with drugs like:

- alcohol
- sleeping pills and tranquillisers (such as benzodiazepines or barbiturates)
- antidepressants
- other opiates (such as morphine, pethidine, methadone or codeine).

Mixing these drugs can lead to drowsiness, sedation, unconsciousness and death. If you are taking other medications or other drugs, tell your doctor when discussing Suboxone Film treatment.

Other health issues

You should not take Suboxone Film if you have:

- severe breathing problems
- recent severe head injury
- severe abdominal pain.

Hepatitis and liver problems

Buprenorphine is an opiate and, in general, opiates do not cause problems for the liver. Suboxone Film, taken in line with your doctor's advice, does not appear to cause problems for the liver.

Many heroin/opiate users — especially those with hepatitis C or those who have had hepatitis B — are concerned that their medications might affect their liver. You should talk about any of your concerns with your doctor.

Suboxone Sublingual Film treatment

Treatment using Suboxone Film has three stages:

- > starting up (getting into treatment and getting the dose right)
- maintenance
- coming off maintenance treatment (withdrawal).

Starting up

What dose do I take?

The 'right dose' varies from person to person, and even varies for the same person from time to time. If your dose is too low, you might not be able to stop using heroin/opiates. If your dose is too high, you might have too many side effects, or feel stoned. The most important thing in this stage is to work closely with your doctor to get to the right dose for you as quickly as possible.

During this stage, many people continue to use some heroin/opiates, although less than they did before starting treatment. This is guite normal; it is difficult to immediately stop using opiates altogether. However, using heroin or other opiates during the first week of treatment could make it harder to stabilise guickly, causing more discomfort for longer periods.

See your doctor regularly and talk about any issues or concerns you have.

Can I use other drugs, too?

It is very dangerous to use benzodiazepines (such as sleeping pills or tranquillisers, including temazepam or diazepam) or alcohol in this stage. The risk of overdose increases in the early stages of treatment, and it increases even more when people use sedatives as well as Suboxone Film.

66 It can be dangerous to take sedatives or other drugs while on Suboxone Film. Check with your doctor before mixing drugs.

Tips for Suboxone Sublingual Film dosing

Before taking Suboxone Film, it's a good idea to drink some water to moisten your mouth, this should help the film dissolve more easily.

- ▶ Try not to smoke (anything) before your dose.
- Avoid drinks that dry out your mouth, such as coke and coffee, before taking your dose.
- Make sure there is a bit of time between cleaning your teeth and being dosed. (Toothpaste and alcohol-based mouthwashes can dry out the mouth.)
- ▶ Make sure your hands are dry. Suboxone Film should be held between 2 fingers by the outside edges of the film.

Chewing gum can help to lubricate the mouth.

A step-by-step guide

- **1.** Place the Suboxone Film under your tongue (close to the base on either side)
- **2.** If you are taking two films at a time, place the other film under your tongue on the opposite side at the same time. Try to avoid having the films touch as much as possible.
- **3.** Keep the films in place until they are completely dissolved.
- **4.** If you are directed to use a third film, place it under your tongue on either side immediately after the first two have dissolved.
- **5.** While Suboxone Film is dissolving, don't chew or swallow the films because less will be absorbed into your bloodstream and it will not work as well.
- 6. Talking, eating or drinking while the films are dissolving can interfere with how well the medication in Suboxone Film is absorbed.

Remember...

If you ever feel that you have swallowed your dose, talk to your pharmacist or doctor.

How do I take Suboxone Sublingual Film?

You put the Suboxone Film under your tongue (take it sublingually) and wait until it dissolves. This will usually take from 4 to 8 minutes.

If you are not used to dissolving a film under your tongue, you will have to concentrate on doing it until you feel comfortable. You should resist any urge to swallow the film. If you do, you will not get the best effect from it. You must dissolve the film, fully, under your tongue.



What are the side effects?

Common side effects

Suboxone Film has a range of side effects. They are very much like Subutex & Suboxone Tablet's side effects, and similar to the side effects of all opiates. Most side effects occur in the first week or two of treatment and settle down after that. Persistent side effects will stop when your treatment stops.

The most commonly reported side effects are:

- > sleep problems (such as difficulty falling asleep and disturbed sleep)
- cold and flu-like symptoms
- mood swings
- headaches, which are very common early in treatment but usually settle down in a few days
- constipation (a side effect of all opiates)
- increased sweating (especially after exercise)
- tiredness or drowsiness (especially after a dose), which usually stops within days to weeks
- loss of appetite, nausea and vomiting (which usually stop after a few days)
- ▶ abdominal pain (cramps), which also usually settles down quickly

- skin rashes and itching, which usually settle down within days
- tooth decay, which can be a problem with all opiates. Opiates reduce the production of saliva, which contains antibacterial agents that help to prevent teeth and gum disease
- changes to menstrual cycle (for women)
- lowered sex drive
- respiratory depression, especially when combined with other depressants (such as alcohol or benzodiazepines).

Women and Suboxone Sublingual Film

Many women have irregular periods when using heroin or other opiates. Some women's menstrual cycles return to normal during buprenorphine treatment. Other women continue to have irregular periods. You can still get pregnant even if you are having irregular periods.

Driving and operating other machinery

Like all opiates, Suboxone Film can make you drowsy and slow down your reaction time. This can affect your ability to drive motor vehicles, operate machinery or play sport. This happens especially:

- in the first few weeks of treatment
- when you are adjusting your dose
- if you mix your dose with alcohol or other sedatives, which is also very dangerous due to the risk of overdose or death.

Each State and Territory has rules about driving while taking medication. Ask your doctor about what rules apply where you are and which activities you should avoid (and for how long)

Living with side effects

Living with side effects is part of maintenance treatment; for example, many people experience constipation. It is very unlikely that you will have to stop taking buprenorphine (Subutex, Suboxone Tablets or Suboxone Film) because of side effects.

There are things you can do to reduce side effects, so it's important to talk to your doctor or pharmacist about the options.

What is 'precipitated withdrawal'?

Your first dose of buprenorphine (the opiate agonist in Subutex, Suboxone Tablets or Suboxone Film) can cause withdrawal symptoms, because of a process called 'precipitated withdrawal'.

Precipitated withdrawal happens if a person has a lot of opiates (such as heroin or methadone) in their system when they take buprenorphine. Buprenorphine kicks the heroin or methadone off the brain's opiate receptors and occupies the receptors itself. Because buprenorphine has weaker effects than heroin or methadone, this results in a withdrawal reaction.

In other words, taking buprenorphine soon after heroin or methadone displaces one kind of opiate (heroin or methadone) with a weaker kind (buprenorphine), causing withdrawal symptoms ('hanging out').

Symptoms of precipitated withdrawal

Precipitated withdrawal can feel unpleasant, but is not usually as severe as 'cold turkey' withdrawal. Withdrawal is likely to start 30 to 90 minutes after the buprenorphine dose and peak one to two hours after the dose is taken. Withdrawal symptoms can be:

- sweating (hot and cold sweats and shivers)
- nausea and abdominal cramps
- aches and pains
- cravings
- anxiety.

If you go into precipitated withdrawal, there is not much you can do other than wait until it subsides, which it eventually will.

Avoiding precipitated withdrawal

Precipitated withdrawal can be prevented. It is often unpleasant, and drugs (such as heroin or other opiates) are not good at reducing the effects of this kind of withdrawal.

To reduce the risk of precipitated withdrawal, plan your first dose with your doctor, pharmacist and support people.



Plan your first dose with your doctor to avoid precipitated withdrawal.

Before starting Suboxone Film treatment, try to reduce the amount of opiates you are taking. The lower the levels of opiates in your system, the easier your transfer to Suboxone Film will be

Delay your first dose of Suboxone Film until you start to hang out. This is usually at least six hours after using heroin, or 24 hours after your last methadone dose (if the methadone dose is less than 40 mg).

Will I be urine tested?

At any stage of your treatment, your doctor might ask you to take a urine test. They will do this to scientifically establish what substances are in your system. This is a standard procedure to protect you against drug interactions. Drug interactions can be dangerous and you may not be aware of them.

A urine test can detect buprenorphine, benzodiazepines (such as Valium or Xanax), cocaine, amphetamines, cannabis and opiates (such as heroin, morphine or methadone).



Transferring from Subutex or Suboxone Tablets to Suboxone Sublingual Film

Transferring from Subutex or Suboxone Tablets to Suboxone Film is straightforward. These medications contain buprenorphine, so your dose of buprenorphine should not change when you swap from Subutex or Suboxone Tablets to Suboxone Film.

Transferring from methadone to Suboxone Sublingual Film

Transferring from methadone to Suboxone Film is more difficult than starting up from heroin use. This is because methadone is a longer acting opiate, which increases the risk of precipitated withdrawal following the first dose of Suboxone Film. Precipitated withdrawal is more likely to occur (and to be more severe) when transferring from higher methadone doses, when there is a shorter time interval between the last methadone dose and the first Suboxone Film dose, and/or with higher first doses of Suboxone Film. People on high doses of methadone (e.g. 60 mg or more) will have great difficulty in transferring to Suboxone Film. Ideally, people should be stable on low methadone doses (30 mg or less) before swapping to Suboxone Film.

Maintenance

Once you get the dose right for you, you enter the maintenance stage.

What's the point of the maintenance stage?

In this stage, you use Suboxone Film, rather than heroin or other opiates, to prevent withdrawal and alleviate the feeling that you need to use. The medication holds you physically and you don't have the pressures of keeping up with the demands of illicit drug use. This gives you the time and space to take care of other aspects of your life. This might include:

- establishing a more stable personal life
- finding longer term accommodation
- dealing with relationship issues
- getting a job or doing education or training.

How long is the maintenance stage?

Clinical trials have indicated that people generally need maintenance treatment for at least six months for it to be effective. However, the amount of time that a person needs to be in maintenance treatment varies from person to person.

28

You (along with your treatment team) choose how long you need to be in treatment. A good relationship with your treatment team will enable you to negotiate how long you want to be in treatment, what doses you need to be on and any other assistance you need.



The decision to start and finish treatment remains with you.



What are the dispensing arrangements?

Supervised dosing

People on opiate substitution therapy are usually required to take their dose while at the pharmacy or clinic, in view of the pharmacist. This arrangement ensures the medication is taken as directed, and that it is used safely. This means that you must wait at the pharmacy or the clinic's dispensary while the Suboxone Film dissolves under your tongue.

Unsupervised dosing

Different States and Territories have different guidelines about who is eligible for unsupervised dosing. Depending on your local guidelines, you may be able to 'take away' supplies of Suboxone Film. A pharmacist (or clinic nurse) will supply enough medication until the next clinic visit (usually up to a week's supply at a time for people on Suboxone Film).

Your treatment team will also have to decide whether you are stable enough to be allowed take-away Suboxone Film. In making this decision, they will consider:

- whether you are using heroin or other drugs whether you have been injecting recently
- how regularly you come to your clinic appointments
- your physical and mental health
- if you can safely store Suboxone Film at your home (so that no one else can dip into it).

29

Your treatment team will discuss these issues with you before making a decision.

If you want information about the unsupervised dosing guidelines for your State or Territory, contact your local drug user organisation.

Safe storage of take-away doses

Suboxone Film contains a strong opiate. It is very important that it is only taken, as directed, by the person for whom it is prescribed. It is essential children and young people cannot access the medication as it could be very dangerous for them.

Store take-away doses out of reach of children and young people.

If you have take-away doses of Suboxone Film, you must store them in a place where young children cannot reach them, and other people cannot find them.

What dose will I take?

Your treatment team and you together will decide what the best dose and frequency is for you.

Suboxone Film treatment usually begins with daily dosing until you have stabilised your dose and your drug use (this can take several weeks). After this, your doctor can increase the dose so that most people can take Suboxone Film every second day and some can even be comfortable with a dose every three days — talk to your doctor about this. At the right dose for you (usually 8 mg or more depending on your dosing frequency), Suboxone Film will be effective for at least 24 hours, or up to 2—3 days, and you will feel no withdrawal.

Different people and different situations need different dosing approaches. For example, someone on long-term maintenance treatment might need a dose of 8–24 mg, while someone undergoing withdrawal might need smaller doses, perhaps between 4–12 mg.

It maybe possible to take smaller doses more often if your treatment team agrees to unsupervised dosing.

You should discuss dosing options with your treatment team and always consult your doctor before changing your dose or frequency.

Why do I need a routine?

In the starting up phase, you will have worked out the right dose for you and the right frequency of taking it. To get the best results from the treatment, it is important that you stick to this dose and frequency.

The best dose and frequency depends on the individual. Some people prefer smaller doses, often. Others prefer less frequent but larger doses. Some people prefer morning doses. Other people prefer to take their dose at night.

Getting the dose right might take a bit of trial and error, time and patience. Keep a diary of the size and frequency of different doses, and how your body responds to them. This will help you work out the right routine for you. Once you have found the right routine, try to stick to it.

What if I miss a dose?

Sometimes, you may miss a dose of Suboxone Film. If you do miss a dose, don't double up on your next dose. Just continue on with your regular routine. If you are entitled to take-aways, you will be left with an extra dose at the end of the dosing period. You should let your pharmacist or doctor know about this.

Transferring to other maintenance treatments

You might decide that Suboxone Film is no longer the best maintenance treatment for you, and that another treatment might be better. Or you might want to move to an area where Suboxone Film is not available.

If you don't think your current treatment is working well for you, discuss it with your treatment team.

Transferring from Suboxone Sublingual Film to Subutex

Transferring from Suboxone Film to Subutex is straightforward. Both medications contain buprenorphine, so your dose of buprenorphine should not need to change when you swap from Suboxone Film to Subutex.

Transferring from Suboxone Sublingual Film (buprenorphine) to methadone

Transferring from Suboxone Film to methadone is also reasonably easy. For example, if you take Suboxone Film daily, then the day after you stop taking Suboxone Film you can start taking methadone. If you take Suboxone Film every two days, then you start methadone the second day after stopping Suboxone Film.

It may take several days to get to the right methadone dose for you. So keep in close touch with your treatment team until you get your methadone dose right.

Transferring from Suboxone Sublingual Film (buprenorphine) to naltrexone

Naltrexone blocks the effects of heroin or other opiates. It can be useful for some people in reducing their cravings and staying off opiates. However, if you stop Suboxone Film and start naltrexone, you may experience withdrawal symptoms. Transferring from Suboxone Film to naltrexone should be done under medical supervision, and with preplanning. Naltrexone can be started within days after the last dose of Suboxone Film maintenance treatment.

32

Coming off maintenance treatment

How long you spend on maintenance treatment varies from person to person, and it's your decision. Your doctor will usually recommend that you come off maintenance treatment very slowly.



You may find that coming off maintenance treatment works best when you have stopped using for a long time and you feel you can cope with stresses in life without feeling the need to use heroin or other opiates. The amount of time it takes to come off maintenance treatment varies from person to person.

Most people find it easy to stop using heroin and other opiates during their maintenance treatment, but hard not to use when they are coming off treatment. Many people go back to using heroin/opiates (relapse) after stopping longer term treatment. Although relapses are common, you can minimise your chances of using again with support from a drug and alcohol support worker or your local drug user organisation. It is important to understand that this is a common experience. Coming off maintenance treatment is not particularly easy.

Things that will help you successfully come off maintenance treatment are:

- coming off maintenance treatment when you feel you are ready to do it
- > setting personal goals that you really want to achieve, and feel you can achieve
- organising support in advance from a support person or a drug user organisation
- ▶ talking to people who have come off treatment about strategies that worked for them.

33

Your treatment team can help you decide about the best time for you to come off maintenance treatment.

Problems and complaints

Problems and complaints

At times you may find that you have problems with your service providers. This could be the way you are treated, not having input into your treatment program, or having difficulties at the pharmacy. It is important to remember that as a consumer of health services you have rights. If you are experiencing problems with any of your treatment providers, here are a few tips:

- ▶ If you are able to, raise these issues directly with your service provider, as problems are often caused by a misunderstanding between people. The failure of a health service to fulfil any of its responsibilities may be evidence of professional negligence.
- Check out your service provider's complaints and suggestions policy. Ask for a copy and take action. In many cases, it is illegal to treat someone unfavourably because they have made a complaint. Independent complaints authorities (Health Care Complaints and Pharmacotherapy Complaints, Advice and Advocacy Services), Legal Aid Commissions and community legal centres can provide further information about this.
- Contact your local drug user organisation for information, advice and support in making a complaint.
- ▶ Remember, as a user of health services you have rights!

Useful contacts

Telephone services

Confidential and anonymous 24-hour telephone services provide counselling and referral. They can help you find a local Suboxone Film treatment program.

Alcohol and Drug Information Services

ACT

(02) 6207 9977

New South Wales

(02) 9361 8000 1800 422 599 (country)

Northern Territory

1800 131 350 Darwin (08) 8922 8399 Alice Springs (08) 8951 7580

Queensland

(07) 3837 5989 1800 177 833 (country)

South Australia

(08) 8363 8618 1300 131 340

Tasmania

1800 811 994 Hobart (03) 9416 1818

Victoria

1800 888 236

Western Australia

(08) 9442 5000 1800 198 024 (country)

Treatment advocacy and complaints

A confidential advocacy and complaints service is available in some Australian states for people on a pharmacotherapy program such as methadone, buprenorphine or naltrexone. These services provide assistance for people experiencing problems with their program.

New South Wales

Victoria

PPharmacotherapy Advocacy Mediation and Support (PAMS).....(03) 9329 1500 or 1800 443 844

Western Australia

Opiate Replacement Pharmacotherapy
Advocacy and Complaints Service (ORPACS).....(08) 9227 7866

For people in other States, contact your local drug user organisation for information, advice and support in making a complaint, or contact your local alcohol and drug information service for more information.

Drug user organisations

The Australian Injecting & Illicit Drug Users League (AIVL) is the national drug users organisation. State and Territory drug user organisations are members of AIVL. For more information on the AIVL national network, visit the AIVL website at: www.aivl.org.au or phone the AIVL office on the number below.

National	AIVL (02) 6279 16			
ACT	CAHMA	(02) 6279 1670		
Queensland	QUIHN (Brisbane) QuIVAA	(07) 3620 8111 1800 172 076		
NSW	NUAA	(02) 8354 7300 1800 644 413		
NT	NTAHC	(08) 8941 1711		
South Australia	SAVIVE	(08) 8334 1699		
Tasmania	TasCAHRD	(03) 6234 1242		
Victoria	HRV	(03) 9329 1500 1800 443 844		
Western Australia	WASUA	(08) 9321 2877		

Peer support

Narcotics Anonymous (NA)

1300 652 820

Recorded information about NA in Australia, including support group meeting times and locations. To find out more about Narcotics Anonymous, visit the NA website at: www.naoz.org.au

Self Help Addiction Resource Centre (SHARC)

(03) 9573 1700

Self help and peer support, information and resource centre, telephone help line, library services and access to up-to-date referral and service information. Services include youth residential programs, counselling, self help/support groups, Family Drug Help.

Your program

Notes			

PLEASE ENSURE YOU KEEP THIS CARD WITH YOU AT ALL TIMES

This patient is taking the drug buprenorphine/naloxone (Suboxone Sublingual Film)
Name of physician:
Physician's telephone number:
Patient's name:
Patient's telephone number::
Date treatment was initiated:
In an emergency, call 000 for an ambulance. For further information, call your State/Territory Alcohol & Drug Information Service (ADIS) or Reckitt Benckiser during business hours on 1800 022 046 (toll free).

TO THE MEDICAL PERSONNEL TREATING ME IN AN EMERGENCY

This patient is taking the drug buprenorphine/naloxone (Suboxone Sublingual Film), a combination partial opiate agonist and antagonist.

Patients taking buprenorphine/naloxone may have a diminished response to opiate medications (including those for the management of cough or pain). Opiate containing preparations should be avoided when non-opiate therapy is available as an alternative.

In an emergency situation requiring pain relief in patients taking Suboxone Film, a suggested plan of management is regional anaesthesia, conscious sedation with a benzodiazepine, use of non-opioid analgesics or general anaesthesia.

In a situation requiring opiate analgesia, the dose of opiate required may be greater than usual. A rapidly acting opiate analgesic which minimises the duration of respiratory depression should be used. The dose of opioid medication should be titrated against the patient's analgesic and physiological response, with close monitoring by trained staff

Overdose with buprenorphine/naloxone alone is very uncommon. In a situation that a patient taking buprenorphine/naloxone has overdosed and is unconscious, high doses of naloxone (up to 10–15 times normal doses) may be required to reverse the opiate intoxication. It is recommended that naloxone doses be titrated upwards until the desired response is achieved. The patient should be monitored for at least several hours afterwards.



