

Buprenorphine Sandoz[®] Transdermal Drug Delivery System

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 Buprenorphine Sandoz?

Buprenorphine Sandoz Transdermal Drug Delivery System (“patches”) contains the active ingredient buprenorphine. Buprenorphine Sandoz patches are used for the management of pain severe enough to require daily, long-term opioid treatment and for which other forms of treatment have failed or are otherwise inappropriate to provide sufficient management of pain.

For more information, see Section [1. Why am I using Buprenorphine Sandoz?](#) in the full CMI.

2. What should I know before I use Buprenorphine Sandoz?

Do not use if you have ever had an allergic reaction to buprenorphine 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 Buprenorphine Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Buprenorphine Sandoz 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 Buprenorphine Sandoz?

- Your doctor will tell you exactly how much to take.
- Follow the instructions given to you by your doctor or your pharmacist.

More instructions can be found in Section [4. How do I use Buprenorphine Sandoz?](#) in the full CMI.

5. What should I know while using Buprenorphine Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Buprenorphine Sandoz.• Tell your doctor or pharmacist if you are taking any other medicines that you use to help you relax, anything that contains alcohol (like cough syrup) or other medicines that treat pain.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take more than your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Buprenorphine Sandoz may cause drowsiness. If affected, do not drive a vehicle or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol. Alcohol may make you feel more sleepy and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using Buprenorphine Sandoz?](#) in the full CMI.

6. Are there any side effects?

Buprenorphine Sandoz may cause constipation, nausea, vomiting, dizziness, drowsiness and be habit forming if taken frequently or over long periods.

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.

WARNING:**Limitations of use**

Buprenorphine Sandoz should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Buprenorphine Sandoz pose risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Buprenorphine Sandoz can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Buprenorphine Sandoz and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using Buprenorphine Sandoz

Using Buprenorphine Sandoz with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Buprenorphine Sandoz.

Buprenorphine Sandoz®

Active ingredient(s): buprenorphine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Buprenorphine Sandoz. **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 Buprenorphine Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Buprenorphine Sandoz?](#)
- [2. What should I know before I use Buprenorphine Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Buprenorphine Sandoz?](#)
- [5. What should I know while using Buprenorphine Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Buprenorphine Sandoz?

Buprenorphine Sandoz contains the active ingredient buprenorphine. Buprenorphine Sandoz belongs to a group of medicines called opioid analgesics.

Buprenorphine Sandoz are indicated for the management of severe pain where:

- other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain, and
- the pain is opioid-responsive, and
- requires daily, continuous, long-term treatment.

2. What should I know before I use Buprenorphine Sandoz?

Warnings

Do not use Buprenorphine Sandoz if:

- you are allergic to buprenorphine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have acute breathing difficulties such as bronchitis or asthma
- you have severe abdominal pain with bloating, cramps or vomiting
- you have a condition where your small bowel does not work properly
- you take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- you are pregnant or in labour.

Check with your doctor if you:

- are severely drowsy, have a reduced level of consciousness or are feeling faint or dizzy upon standing
- have heart problems or heart disease
- have low blood pressure
- have chronic lung disease
- suffer from sleep apnoea (temporarily stop breathing while you sleep)
- have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- suffer from convulsions, fits or seizures

- have a head injury, brain tumour or increased pressure in your head
- are about to have surgery, had recent gastrointestinal surgery or have had other surgery in the last 24 hours
- have chronic liver or kidney disease
- have increased prostate size or difficulty passing urine
- have problems with your gall bladder
- have problems with or recent surgery of your bile duct
- have inflammation of the pancreas
- have adrenal glands which are not working properly
- have an underactive thyroid gland
- have a severe mental condition involving losing contact with reality or an inability to think clearly
- have an addiction or history of abuse of alcohol, opioids or other drugs.

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.

Buprenorphine Sandoz given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Low levels of opioid analgesics have been detected in human milk.

Addiction

You can become addicted to Buprenorphine Sandoz even if you use them exactly as prescribed. Buprenorphine Sandoz may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you using Buprenorphine Sandoz. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop using Buprenorphine Sandoz suddenly, so it is important to use it exactly as directed by your doctor.

Tolerance

Tolerance to Buprenorphine Sandoz may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicines for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

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 Buprenorphine Sandoz and affect how it works.

Using Buprenorphine Sandoz with medicines that can make you feel drowsy may result in severe drowsiness, decreased awareness, breathing problems, coma and death. These medicines include:

- sleeping tablets and other sedatives (including benzodiazepines and barbiturates)
- gabapentinoids
- cannabis
- antihistamines
- anxiolytics
- general anaesthetics
- antiemetics
- antidepressants (including tricyclic antidepressants)
- antipsychotics (including phenothiazines)
- neuroleptics
- beta-blockers (medicines used to treat high blood pressure)
- other opioids
- alcohol.

Buprenorphine Sandoz may enhance the action of neuromuscular blocking agents (medicines used to relax muscles) and affect your breathing.

Buprenorphine Sandoz may increase the anticoagulant activity of coumarin and other anticoagulants (medicines used to prevent blood clots).

Buprenorphine Sandoz should not be used if you are taking non-selective monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

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

4. How do I use Buprenorphine Sandoz?

How much to use

Different strengths of Buprenorphine Sandoz are available:

- your doctor will decide which strength is suitable to control your pain;
- during treatment, your doctor may change the patch you use to a different strength if necessary, or tell you to use a combination of up to two patches. Do not cut

or divide the patch or use a higher dose than recommended.

The maximum total dose must not exceed 40 microgram/hour and you should not apply more than two patches

at the same time. If one 40 microgram/hour patch is applied, no additional patches should be applied. Follow the instructions your doctor or pharmacist gives you exactly.

How to use Buprenorphine Sandoz

- Each patch is applied onto the skin and lasts for seven days.
- After seven days, remove the patch and apply a new patch to a different site.

If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

Using the patch for the first time

- The first Buprenorphine Sandoz you use may take up to three days to reach its full effect. This is because buprenorphine needs to be absorbed through the skin and then into the blood before you start to feel the effects.
- Your doctor may prescribe additional medicines to control the pain during this time.

Applying the patch

1. Find a clean skin site on the upper outer arm, upper chest, upper back or the side of the chest. Do not place the patch onto skin that is red, burnt or injured.
2. Make sure the site is nearly hairless and has no large scars. Remove any hair by cutting with scissors if you have to, but do not shave the chosen area as this may injure the skin.
3. Apply the patch to an area of skin that is clean and dry and has not had a patch applied to it for three to four weeks. If necessary, wash the area with water only. Do not use soap, alcohol or a coarse cloth to clean. Dry the area completely after washing with water. Do not apply oils or lotions to the chosen area as this may prevent your patch from sticking properly.
4. Each patch is sealed in a pouch. Just before use, open the pouch by cutting as close to the edge as you can. Take out the patch. Do not use the patch if the pouch is torn or looks like it has been tampered with or the pouch seal is broken.
5. The sticky side of the patch is covered by a silver backing foil. Carefully peel off the smaller portion of the scored backing foil. Try not to touch the sticky part of the patch. Press the sticky edge of the patch, which had the backing foil removed, to the edge of the chosen skin site. Peel off the remaining foil and press the patch firmly onto the skin with the palm of the hand and count slowly to 30.
6. Make sure the whole patch is in contact with the skin especially around the edges. If the edges of the patch

begin to peel off, they may be taped down with a suitable skin tape.

7. Wash your hands with clean water when you have finished applying the patch.

Wearing the patch

You should wear the patch continuously for seven days. Bathing, showering or swimming should not affect the patch. However, it is a good idea to keep the patch dry whenever possible.

Do not expose the patch to direct heat from electric blankets, heat pads, heated water beds, heat or tanning lamps, intensive sunbathing, hot water bottles, long hot baths, saunas or hot spa baths while you are using Buprenorphine Sandoz. Direct exposure to such heat may cause an increase in the amount of buprenorphine absorbed by the skin, resulting in possible overdose and death.

External heat may also prevent the patch from sticking properly.

In the event your patch falls off before it needs changing, do not use the same patch again. Apply a new patch to a different site straight away.

If you feel the effect of the patch is too weak or too strong, talk to your doctor.

Tell your doctor if you experience skin rash while wearing the patch. Skin reaction may cause infection, your doctor will tell you what to do.

Changing the patch

Change your patch on the same day at the same time each week.

For example, if you start using your patch on Monday at 9 am, change your patch the following Monday at 9 am.

1. After seven days, take the old patch off.
2. Fold the used patch in half so that the sticky side stick to itself.
3. Dispose of the used patch in a safe place, where children cannot reach it.
4. Apply a new patch straight away to a difference area of the skin, following the steps under 'Applying the patch'.

A new patch should not be applied to the same skin site for three to four weeks.

If you forget to change Buprenorphine Sandoz

Remove the old patch and apply a new patch as soon as you remember. Also make note of the day as your usual day of changing the patch may now be different. If you are late changing your patch, your pain may return. In this case, contact your doctor.

Do not apply twice the number of patches to make up for the patch that you forgot to change on time.

Using extra patches will increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering the day and time to change your patch, ask your pharmacist for some hints.

If you use too much Buprenorphine Sandoz (overdose)

If you think that you or someone else may have used too much Buprenorphine Sandoz, you may need urgent medical attention.

You should immediately:

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

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately remove the patch(es) and call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Buprenorphine Sandoz that were prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits.

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

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 Buprenorphine Sandoz?

Things you should do

Call your doctor straight away if you:

- become pregnant
- feel your pain is getting worse

Remind any doctor, dentist or pharmacist you visit that you are using Buprenorphine Sandoz.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Tell your doctor if you find that you cannot concentrate or that you feel more sleepy than normal when you start using this medicine or when the dose is increased. This feeling should wear off after a few days.

Tell your doctor if you develop a high fever. At high body temperatures, the amount of buprenorphine absorbed

into the skin may increase which may increase the chance of unwanted side effects.

Tell your doctor if you suffer from nausea or vomiting when using Buprenorphine Sandoz. Your doctor may prescribe some medicine to help.

Tell your doctor if using Buprenorphine Sandoz causes constipation. Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help manage this.

If the patch accidentally adheres to another person (e.g. a family member sharing the same bed): remove the patch immediately, wash the area thoroughly and contact your doctor.

Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as unsteadiness, dizziness, drowsiness or confusion which may increase the risk of fall.

Things you should not do

The maximum total dose must not exceed 40 micrograms/hour and you should not apply more than two patches at the same time. If one 40 micrograms/hour patch is applied, no additional patches should be applied.

Do not stop using this medicine suddenly. If you stop taking Buprenorphine Sandoz suddenly, your pain may worsen and you may experience withdrawal symptoms.

Do not use Buprenorphine Sandoz to treat any other complaint unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not expose the patch to direct heat sources, or wear it in saunas or hot tubs and avoid intensive sunbathing.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Buprenorphine Sandoz affects you.

Buprenorphine Sandoz may cause drowsiness or impair mental and/or physical ability in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make you feel more sleepy, and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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. A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If the medicine is damaged, 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.

After removing the used patch, fold it over on itself so that the adhesive side of the patch sticks to itself, and dispose of it safely where children cannot reach it.

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
<p>Gastrointestinal and urinary related:</p> <ul style="list-style-type: none"> constipation nausea or vomiting difficultly urinating <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> dizziness drowsiness headache <p>Allergy related:</p> <ul style="list-style-type: none"> itching at the patch site or other areas of the body skin rash sweating 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Breathing related:</p> <ul style="list-style-type: none"> difficulty breathing or shallow breathing <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> light-headedness, fainting or dizziness especially when standing up changes in mood drowsiness or feeling extremely sedated 	<p>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.</p>

<ul style="list-style-type: none"> feeling disorientated and having nightmares <p>Heart related:</p> <ul style="list-style-type: none"> slow or noticeable heartbeats <p>Gastrointestinal and urinary related:</p> <ul style="list-style-type: none"> severe stomach pain with nausea or vomiting difficulty urinating <p>Allergy related:</p> <ul style="list-style-type: none"> shortness of breath, swelling of the face, lips, tongue or other parts of the body 	
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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. 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 Buprenorphine Sandoz contains

Active ingredient (main ingredient)	
	Buprenorphine
	Buprenorphine Sandoz 5 patches contain a total of 5 mg buprenorphine and release buprenorphine at a rate of 5 micrograms/hour.
	Buprenorphine Sandoz 10 patches contain a total of 10 mg buprenorphine and release buprenorphine at a rate of 10 micrograms/hour.
	Buprenorphine Sandoz 15 patches contain a total of 15 mg buprenorphine and release buprenorphine at a rate of 15 micrograms/hour.
	Buprenorphine Sandoz 20 patches contain a total of 20 mg buprenorphine and release

	<p>buprenorphine at a rate of 20 micrograms/hour.</p> <p>Buprenorphine Sandoz 25 patches contain a total of 25 mg buprenorphine and release buprenorphine at a rate of 25 micrograms/hour.</p> <p>Buprenorphine Sandoz 30 patches contain a total of 30 mg buprenorphine and release buprenorphine at a rate of 30 micrograms/hour.</p> <p>Buprenorphine Sandoz 40 patches contain a total of 40 mg buprenorphine and release buprenorphine at a rate of 40 micrograms/hour.</p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • levulinic acid • oleyl oleate • povidone • Duro Tak 387-2054 (ARPING No 4573) • Polyurethane Tape (Cover Patch 3M Co-Tran 9698; ARPING No 111126)

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

What Buprenorphine Sandoz looks like

Buprenorphine Sandoz patches are available in seven strengths, individually packed in sachets and are supplied in cartons containing two sachets.

Buprenorphine Sandoz 5 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 5 µg/h" (AUST R 269679).

Buprenorphine Sandoz 10 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 10 µg/h" (AUST R 269671).

Buprenorphine Sandoz 15 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 15 µg/h" (AUST R 269676).

Buprenorphine Sandoz 20 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 20 µg/h" (AUST R 269678).

Buprenorphine Sandoz 25 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 25 µg/h" (AUST R 319413).

Buprenorphine Sandoz 30 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 30 µg/h" (AUST R 319414).

Buprenorphine Sandoz 40 patches are a pale yellowish-brown rectangular patch with rounded edges imprinted in black ink "Buprenorphinum 40 µg/h" (AUST R 319415).

Who distributes Buprenorphine Sandoz

Buprenorphine Sandoz patches are supplied in Australia by:

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road,
 Macquarie Park,
 NSW 2113, AUSTRALIA
 Tel: 1800 726 369

This leaflet was prepared in October 2021.