BUPREDERMAL®

Transdermal Drug Delivery System

Buprenorphine (boo-pree-nor-feen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BUPREDERMAL® Transdermal Drug Delivery System ("patches").

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What BUPREDERMAL patches are used for

BUPREDERMAL patches contain buprenorphine. Buprenorphine belongs to a group of medicines called opioid analgesics.

BUPREDERMAL patches are used to relieve moderate to severe pain.

Opioid analgesics such as buprenorphine have been used to treat pain for many years. Your doctor, however, may prescribe it for another purpose.

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

BUPREDERMAL patches act through the skin. After application, buprenorphine passes through the skin into the blood. Each patch should be worn for seven days.

As with all strong painkillers, your body may become used to you using buprenorphine patches. Using them may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop using buprenorphine suddenly, so it is important to use it exactly as directed by your doctor.

This medicine is only available with a doctor's prescription. Selling or giving away BUPREDERMAL is against the law.

Before you use BUPREDERMAL patches

When you must not use them

Do not use BUPREDERMAL patches if you:

- have any breathing problems or have a condition where your lung function is severely impaired
- have confusion and shaking due to stopping drinking alcohol
- have just had an operation or are about to have surgery on your spine for pain relief in the next 24 hours
- suffer from myasthenia gravis, a condition in which the muscles become weak and tire easily
- are taking medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- are dependent on opioids such as morphine, oxycodone, pethidine, fentanyl or methadone. Using BUPREDERMAL patches after using these medicines can cause the onset of withdrawal symptoms.

Do not use BUPREDERMAL patches if you are allergic to buprenorphine, opioid analgesics or any of the ingredients listed at the end of this leaflet.

Do not use this medicine after the expiry date (EXP) printed on the pack.
If you use it after the expiry date has passed, it may not work very well.

Do not use it if the packaging is torn or shows signs of tampering.

Do not use this medicine if you are pregnant or plan to become pregnant whilst using this medicine.
Like most medicines of this kind, BUPREDERMAL patches should not be used during pregnancy. Your doctor can discuss with you the risks of using it if you are pregnant.

Do not give this medicine to a child or adolescent younger than 18 years of age.
Safety and effectiveness in children younger than 18 years have not been established.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- are severely drowsy or have a reduced level of consciousness
- suffer from irregular or fast heartbeats or changes in the way the heart beats
- illness with high fever
- convulsions, fits or seizures
- head injury, brain tumour or increased pressure in your head
- shock (rapid and shallow breathing, cold and clammy skin, a rapid and weak pulse, dizziness, weakness and fainting)
- severe or long-term problems with your liver
- long-term problems with your kidneys
- low blood pressure including from having low blood volume
- increased prostate size
- problems with or recent surgery of your bile duct or gall bladder problems
- recent surgery on your abdomen
- inflammation of the pancreas
- adrenal glands not working properly
- inflammatory bowel disease
- underactive thyroid gland
- have an addiction or history of abuse of alcohol or drugs.

Tell your doctor whether you have used an opioid before.

Tell your doctor if you are breastfeeding or planning to breastfeed.
BUPREDERMAL patches should not be used by breastfeeding women as buprenorphine can pass into the breastmilk and can affect the baby.

If you have not told your doctor about any of the above, tell them before you start using BUPREDERMAL patches.

Taking other medicines

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

Some medicines and alcohol may interfere with BUPREDERMAL patches. These include:

- other pain relievers including other opioids and particularly other long-acting (extended-release) opioid pain medicines
- medicines to treat depression, anxiety, psychiatric or mental disorders. Medicines for depression belonging to a group called monoamine oxidase inhibitors must be stopped 14 days before BUPREDERMAL patches are used
- medicines to help you sleep
- medicines to put you to sleep during an operation or procedure
- quinidine, calcium channel blockers and other medicines to treat abnormal heart rhythms
- medicines to treat seizures
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- medicines to stop nausea or vomiting e.g. metoclopramide or prochlorperazine
- medicines to treat fungal infections e.g. fluconazole or itraconazole
- medicines to treat bacterial infections e.g. rifampicin, macrolide antibiotics
- medicines to treat HIV infections
- alcohol.

These medicines and alcohol may be affected by BUPREDERMAL patches, may affect how well the patches work or may increase side effects. You may need to use different amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to use BUPREDERMAL patches

How much to use

Different strengths of BUPREDERMAL patches 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 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. Follow the instructions your doctor or pharmacist gives you exactly.

How to use the patch

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.

Using the patch for the first time

The first BUPREDERMAL patch 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 heat sources such as heating pads, hot water bottles, electric blankets, heat lamps, saunas, hot tubs or heated water beds etc. and avoid intensive sunbathing.
Heat may cause more medicine than normal to be absorbed and lead to an increase in side effects. External heat may also prevent the patch from sticking properly.

In the event that 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 that the effect of the patch is too weak or too strong, talk to your doctor.

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 sticks 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 different 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 it

Remove the old patch and apply a new patch as soon as you remember. Also make a 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.

How long to use the patches

Continue using the patches for as long as your doctor tells you.

If you stop using BUPREDERMAL patches suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea, stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

If you receive too much (overdose)

If you have received an overdose, remove all patches and immediately telephone your doctor or the Poisons Information Centre (Australia: telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital. This also applies if someone else has accidentally used your patches.

Keep telephone numbers for these places handy.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

If someone has overdosed they may experience difficulties in breathing,

become drowsy and tired, feel sick, vomit, have constricted pupils, have very low blood pressure or slow heart rate, and possibly may even become unconscious or die.

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

While you are using BUPREDERMAL patches

Things you must do

Use BUPREDERMAL patches exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist that you are using BUPREDERMAL patches.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine.
It may affect other medicines used during surgery.

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked.

Tell your doctor if your pain is getting worse, or if you are having frequent breakthrough pain.
Tolerance to buprenorphine may develop which means that the effect of the medicine may decrease with continued use. If this happens, your doctor may review your dose so that you get adequate pain relief.

Keep enough BUPREDERMAL patches with you to last over weekends and holidays.

Store BUPREDERMAL away from children and in a safe place to prevent theft and abuse.

Things you must 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 use BUPREDERMAL patches to treat any other complaint unless your doctor tells you to.

Do not give your medicine to anyone else, even if you think they may have the same condition as you. They may experience side effects and require medical attention.

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

Do not stop using your medicine or change the dosage without checking with your doctor.
Over time your body may become used to you having buprenorphine so if you stop using it suddenly, your pain may worsen and you may have unwanted withdrawal symptoms. This is called physical dependence.

If you need to stop using this medicine, your doctor will gradually reduce the amount you use each day, if possible, before stopping the medicine completely.

The pain-relieving effect of the BUPREDERMAL patch is maintained for some time after removal of the patch. You should not start another opioid analgesic (strong pain medicine) within 24 hours after removal of the patch.

Things to be careful of

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

Do not drive or operate machinery until you know how BUPREDERMAL patches affect you.
BUPREDERMAL patches may cause drowsiness, dizziness or may affect alertness whilst being worn or for at least 24 hours after the patch is removed. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

Be careful when drinking alcohol while you are taking this medicine.
Drinking alcohol whilst using BUPREDERMAL patch may make you feel more sleepy and increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

What to do if the patch accidentally adheres to another person:
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. Do this even if there are no signs of discomfort or drowsiness.

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 a fall.

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

Tell your doctor if using BUPREDERMAL patches 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.

There is potential for abuse of buprenorphine and the development of addiction to buprenorphine. It is important to discuss this issue with your doctor.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, most of the time they are not. Side effects from using BUPREDERMAL patches tend to reduce over time except for constipation. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.
Not everybody experiences them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using BUPREDERMAL patches.

This medicine helps most people with pain, but it may have unwanted side effects in some people. Other side effects not listed here may also occur.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- mild abdominal problems such as feeling sick (nausea), loss of appetite, constipation or diarrhoea
- weight loss
- dry mouth or changes in taste
- sweating
- feeling anxious or nervous or having trouble sleeping
- shaking or tremors
- fatigue, feeling of tiredness, drowsiness, or lack of energy
- trouble with your balance
- new problems with your eyesight
- itching at the patch site or other areas of your body
- redness or rash at the patch site
- dry skin
- swelling, including but not only, of the legs or ankles.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- stomach discomfort or pain, vomiting or indigestion
- feeling deep sadness
- fainting or dizziness especially when standing up
- noticeable heartbeats
- headache or confusion
- unusual weakness or loss of strength or unusual sensations in your limbs.

If any of the following happen, remove the BUPREDERMAL patch and go to Accident and Emergency at your nearest hospital:

- your breathing slows or weakens
- you have an allergic reaction: shortness of breath, wheezing, shallow or difficult breathing; swelling of the tongue, throat, face, lips or other parts of the body; rash, itching or hives on the skin
- fast or irregular heartbeats
- chest pain.

The previous list includes very serious side effects. You may need urgent medical attention or hospitalisation.

When seeking medical attention, take this leaflet and the used patch or any remaining patches with you to show the doctor.

After using BUPREDERMAL patches

Storage

Keep your patches in the pouch until it is time to use them.
If you take the patch out of the pouch they may not keep as well.

Keep your patches in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car.
Heat and damp can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist how to dispose of medicines no longer required.

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.

Product description

What it looks like

BUPREDERMAL patches are either rectangular or square with rounded corners. They are beige in colour. Each BUPREDERMAL patch is printed with the trade name and the strength in blue ink. Each strength is a different size. The higher the strength, the larger the size.

BUPREDERMAL® patches are supplied in cartons containing two individually packaged patches.

Ingredients

BUPREDERMAL® patches contain buprenorphine base as the active ingredient and are available in seven different strengths:

BUPREDERMAL® 5 patches are square, beige-coloured patches which contain a total of 5 mg buprenorphine and release buprenorphine at a rate of 5 micrograms/hour.

BUPREDERMAL® 10 patches are rectangular, beige-coloured patches which contain a total of 10 mg buprenorphine and release buprenorphine at a rate of 10 micrograms/hour.

BUPREDERMAL® 15 patches are rectangular, beige-coloured patches which contain a total of 15 mg buprenorphine and release buprenorphine at a rate of 15 micrograms/hour.

BUPREDERMAL® 20 patches are square, beige-coloured patches which contain a total of 20 mg buprenorphine and release buprenorphine at a rate of 20 micrograms/hour.

BUPREDERMAL® 25 patches are rectangular, beige-coloured patches which contain a total of 25 mg buprenorphine and release buprenorphine at a rate of 25 micrograms/hour.

BUPREDERMAL® 30 patches are rectangular, beige-coloured patches which contain a total of 30 mg buprenorphine and release buprenorphine at a rate of 30 micrograms/hour.

BUPREDERMAL® 40 patches are rectangular, beige-coloured patches which contain a total of 40 mg buprenorphine and release buprenorphine at a rate of 40 micrograms/hour.

Inactive ingredients:

The patches also contain:

- levulinic acid
- oleyl oleate
- povidone
- Duro Tak 387-2051
- Duro Tak 387-2054
- polyethylene terephthalate.

Supplier

BUPREDERMAL patches are supplied in Australia by:

Mundipharma Pty Limited
ABN 87 081 322 509
88 Phillip Street
Sydney NSW 2000
Phone: 1800 188 009

® BUPREDERMAL is a registered trade mark

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Australian Registration numbers for BUPREDERMAL® patches are:

5 micrograms/hr AUST R 234741

10 micrograms/hr AUST R 234742

15 micrograms/hr AUST R 234743

20 micrograms/hr AUST R 234744

25 micrograms/hr AUST R 234745

30 micrograms/hr AUST R 234746

40 micrograms/hr AUST R 234747.

* Not all of strengths and pack sizes are currently marketed in Australia.

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