

FENPATCH® Transdermal Drug Delivery System

contains the active ingredient fentanyl

Consumer Medicine Information

WARNING

Limitations of use

FENPATCH 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

FENPATCH poses 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

FENPATCH can cause life-threatening or fatal breathing difficulties (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 FENPATCH 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.

Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Using FENPATCH 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 FENPATCH.

What is in this leaflet

This leaflet answers some common questions about FENPATCH. 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 FENPATCH against the benefits this medicine is expected to have for you.

If you have any concerns about using FENPATCH, ask your doctor or pharmacist.

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

What FENPATCH is used for

FENPATCH is used for the long-term management of pain that is severe enough to require daily around-the-clock pain relievers, when other treatment options are not able to effectively manage your pain or you cannot tolerate them. FENPATCH is only used in people who have previously been using other opioid-based pain relief. FENPATCH is not used to treat pain that you only have once in a while.

FENPATCH contains a medicine called fentanyl. This strong pain reliever belongs to a group of medicines known as opioid analgesics. Fentanyl relieves pain by blocking the nerves that recognise pain messages from the body.

Each patch is applied onto the skin every 72 hours (3 days). The patch releases a continuous amount of fentanyl that is absorbed through the skin in contact with the patch.

Your doctor may have prescribed FENPATCH for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use FENPATCH

Warning

Opioids can be abused and misused, and you are at risk for opioid addiction, even if you take your dose as prescribed. Opioid addiction, abuse and misuse can lead to overdose and death.

FENPATCH may become habit forming causing mental and

physical dependence. If abused, it may become less able to reduce pain

FENPATCH patches may be retrieved and abused or misused illegally. Please ensure that used patches are concealed and disposed of carefully. Return unused patches to the pharmacy (see Disposal at the end of this leaflet).

Keep used and unused patches where children cannot reach them.

A patch may be tempting to a child. Accidental exposure or ingestion of used or unused FENPATCH patches, particularly in children, may result in breathing difficulties, with slow or shallow breathing, that could lead to death. Improper use including FENPATCH patches sticking to another person can be life threatening.

FENPATCH can cause sleep apnoea (stopping breathing from time to time while sleeping) which can lead to low levels of oxygen in the blood. Tell your doctor if you have a history of sleep apnoea or if anyone notices you stop breathing from time to time whilst sleeping.

Opioids can cause a high level of the hormone 'prolactin' and low levels of sex hormones in the blood. The effects of these hormone changes may include:

- In females – unexpected production of breast milk; loss of menstrual periods.
- In males – enlarged breasts; difficulty getting and keeping an erection (impotence)
- In females or males – decreased sex drive; infertility.

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

Opioids can cause a decreased level of hormones in the blood caused by a problem with the adrenal glands. The effects of these hormone changes may include:

- Nausea, vomiting, loss of appetite, feeling very tired and weak, feeling dizzy, or low blood pressure.

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

Addiction

You can become addicted to Fenpatch even if you take it exactly as prescribed. Fenpatch 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 taking Fenpatch. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Fenpatch suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to Fenpatch 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 medicine 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.

FENPATCH must be stopped by decreasing the dose gradually. Your doctor will tell you how to do this, and will regularly monitor and support any increase in pain or withdrawal symptoms.

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

When you must not use it

Do not use FENPATCH

- if you have an allergy to fentanyl or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- for acute pain or pain following surgery
- for mild or intermittent pain
- at a starting dose greater than 25 micrograms/hour
- if you have any lung conditions or breathing difficulties
- if you have not used any opioid analgesics in the past. This is because you may be likely to experience some of the side effects.

Do not use FENPATCH if the packaging is torn or shows signs of tampering. Do not use FENPATCH beyond the expiry date (month and year) printed on the pack.

Before you start to use it

You must tell your doctor if you

- are pregnant or planning to become pregnant
- are breast feeding or wish to breastfeed
- have or have ever had liver or kidney disease
- have or have ever had problems with your lungs or breathing difficulties
- have sleep apnoea or if anyone notices you stop breathing from time to time while sleeping
- have or have ever had heart disorders

- have or have ever had a brain tumour or head injuries
- have problems with your stomach or intestines such as bowel blockage
- have problems with your immune system or medical conditions which lower your resistance to diseases.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given FENPATCH.

Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or illegal drugs or have a mental illness.

Your doctor will advise you whether or not to use FENPATCH or if you need to adjust the dose or adapt your treatment.

Children

FENPATCH should not be used in children under 12 years of age or in adolescents under 18 years

Taking other medicines

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

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

- medicines that slow down your central nervous system, for example:
 - medicines that make you sleepy, reduce anxiety such as sedatives, hypnotics, sleeping tablets, tranquilisers (benzodiazepines)
 - other opioid medicines
 - medicines used for surgery (anesthetics) and muscle relaxants
 - antihistamines or allergy medicine that makes you drowsy
 - gabapentinoid medicines used to treat epilepsy or nerve pain such as gabapentin and

pregabalin

- alcohol, cannabis or some illegal drugs.

Taking these medicines with FENPATCH may make you even more drowsy, slow down your ability to react, have decreased awareness, breathing difficulties with slow or shallow breathing, coma and death. A change in dose by your doctor may be required if FENPATCH is used with these medicines.

- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs). FENPATCH should not be used concurrently with these medicines and should be initiated until 14 days after cessation of MAOIs. Combination of MAOIs with FENPATCH may increase the risk of serotonin syndrome, a potentially life-threatening condition. Signs and symptoms can include confusion, restlessness, fever, heavy sweating, fast or irregular heart rate, diarrhoea, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles, seizures and unconsciousness.
- other antidepressant medicines belonging to the class selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine re-uptake inhibitors (SNRIs) or tricyclic antidepressants (TCAs) and nefazodone. Combination of these medicines with FENPATCH may increase the risk of serotonin syndrome.
- certain antibiotics used to treat infections such as erythromycin, clarithromycin and troleandomycin.
- certain medicines to treat fungal infections such as fluconazole, ketoconazole, itraconazole, and voriconazole.
- ritonavir and nelfinavir (used to treat AIDS). Do not take

ritonavir or nelfinavir while using FENPATCH, unless you are closely monitored by your doctor.

- if taking rifampicin, carbamazepine, phenobarbital, phenytoin, careful monitoring by your doctor and dose adjustment may be required.
- Idelalisib (cancer treatment)
- certain medicines to treat depression such as nefazodone.
- medicines used to treat mental illness or psychotic conditions and to relieve severe nausea and vomiting, such as phenothiazines.
- certain medicines that act on the heart and blood vessels such as calcium-channel blockers like verapamil, diltiazem and nifedipine.
- certain medicines used to treat arrhythmias such as amiodarone.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Effect on driving and operating machinery

FENPATCH can affect your alertness and ability to drive and operate machinery. Do not drive or operate machinery until your doctor says it is safe.

Effect of alcohol

You must not drink alcohol while using FENPATCH since their combined effect may cause severe drowsiness, decreased awareness, breathing problems, coma and death.

Using FENPATCH

How to use the patch

Adults

Adults FENPATCH is available in five different patches, each with a different size and strength. Your doctor will decide which patch, or combination of patches, is suitable

to control your pain. The lowest effective strength should be used

- Each patch is applied onto the skin and lasts for three days (72 hours).
- After three days, remove the patch and apply a new patch to the skin at a different place.

You should not use more than one patch at a time, unless your doctor authorises otherwise (for example to obtain a dose that cannot be achieved with a single patch). The old patch should be removed before the new patch is applied.

Children

FENPATCH should not be used in children under 12 years of age or in adolescents under 18 years of age who weigh less than 50 kg.

Using it for the first time

The first patch may take up to a day to take effect after it is applied onto the skin. This is because fentanyl is slowly absorbed through the skin into the blood. Your doctor may prescribe additional medicines to control the pain for the first day.

Applying the patch

1. Find an intact and hairless spot of skin on the upper part of your body or on your upper arm. The skin should be healthy and undamaged. Do not place the patch onto skin that is red, burnt or damaged.
2. Trim any excess hair with scissors. Do not shave the hair off since this may affect the skin. If you need to wash the skin before applying the patch, use clean water only. Do not use soap, oils or lotions. The skin should be completely dry before applying the patch.
3. FENPATCH should be applied immediately upon removal from the protective pouch. After locating the tear mark at the edge of the pouch, it should be

carefully torn open and the patch removed.

4. Each FENPATCH has a clear plastic protective liner that can be peeled off in two pieces. After folding the patch in the middle, peel off each part of the protective liner separately.
Patients should avoid touching the adhesive side of the patch.
5. The patch must be applied to the skin by applying light pressure with the palm of the hand for about 30 seconds, making certain the edges are adhering properly.
6. Patients should wash hands afterwards with clean water.

Never cut or divide the patch. Do not use a patch that has been divided, cut or damaged in any way.

You can leave the patch on the skin for three days (72 hours). You may have a bath, shower or swim.

Always write the date and time you applied the patch on the pack. It will help you to use FENPATCH correctly and remember when the next patch is due.

Your doctor may prescribe additional pain relievers to control occasional outbreaks of pain.

Changing the patch

1. After three days (72 hours), remove the patch.
2. Always change your patch at the same time of the day every three days (72 hours).
3. Fold the used patch in half so that the adhesive side sticks to itself. Wrap the folded patch and carefully dispose of it in the garbage.
4. Apply a new patch straight away to a different area of the skin, following the steps under 'Applying the patch'.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If your pain continues, see your doctor who may prescribe additional medicines to help control the pain or change the dose of FENPATCH.

If you forget to use it

If you forget to apply a patch, and are not sure what to do, check with your doctor or pharmacist. If you have trouble remembering when to apply each patch, ask your pharmacist for some hints.

If you receive too much (overdose)

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 FENPATCH that was 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

Other signs of overdose can also include problems with the 'nervous system' (known as toxic leukoencephalopathy).

If you think you or someone else may have used too much FENPATCH, you should immediately:

- remove the patches
- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

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

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.

While you are using FENPATCH

Things you must do

- Always follow your doctor's instructions carefully.
- If you are pregnant or plan to become pregnant, you should inform your doctor, who will decide whether you may use FENPATCH.
- FENPATCH should not be used during childbirth as the medicine can slow the breathing of the newborn child. Prolonged use of FENPATCH during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. If you are breast feeding, you should not use FENPATCH since it may be present in your milk. See your doctor.
- If your pain continues or returns, see your doctor. You may need additional medicines to control the pain or a change in the strength of the FENPATCH.
- Tell your doctor if you develop a fever. At high temperatures, the amount of fentanyl absorbed by the skin increases. Your doctor may need to adjust your FENPATCH dose.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using FENPATCH.

Things you must not do

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 FENPATCH. Direct exposure to such heat may cause an increase in the amount of fentanyl absorbed by the skin, resulting in possible overdose and death.

- Do not use FENPATCH to treat any other complaint unless your doctor says so.
- Do not give the patches to anyone else, even if their symptoms seem similar to yours as they could die from taking it.
- Do not stop using FENPATCH unless your doctor advises you to do so. If you have been using FENPATCH for a long period of time but stop using it suddenly without your doctor's advice, you may experience withdrawal symptoms such as:
 - trouble sleeping, nervousness, restlessness, agitation 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.

Seek your doctor's advice if you experience these symptoms.

Do not cut, break, chew, crush, dissolve, snort or inject FENPATCH. This can result in serious side effects and death.

Things to be careful of

- If the patch accidentally adheres to another person (for example a family member sharing the same bed), remove the patch and call triple zero (000). Do this even if there are no signs of discomfort or drowsiness.

- FENPATCH can affect your alertness and ability to drive and operate machinery. Do not drive or operate machinery until you know how this medicine affects you.
- Different brands of fentanyl patches may vary in size, shape, colour or adhesiveness. **DO NOT switch brands of fentanyl patches unless your doctor and pharmacist authorise it.**

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Tell your doctor if you experience any of the following:

- nausea, vomiting, constipation, dry mouth, diarrhoea, uncomfortable feeling in stomach or belching after eating, indigestion, blockage of the bowel.
- problems with the movement of food or drink through the food pipe.
- low blood pressure, headache, weakness or dizziness, high blood pressure, being less alert or aware, or loss of consciousness.
- blurred vision.
- sleepiness, confusion, hallucinations, euphoria, depression, loss of appetite, anxiety, trouble sleeping, agitation, loss of memory, pins and needles.
- stopping breathing from time to time whilst sleeping (sleep apnoea)

- skin rash (local redness and itch at the site of the patch is usually mild and resolves when the patch is removed).
- thinning or redness where the patch has been on the skin; ulcer (sore) where the patch has been on the skin.
- unusual tiredness or weakness, feeling of body temperature change, swelling of the feet, ankles and hands.

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- slow heart beat.
- fast heart beat.

REMOVE the FENPATCH patch and tell your doctor immediately or go to the Emergency Department at your nearest hospital if the following happens:

- breathing slows or weakens.
- temporarily stopped breathing
- difficulty in breathing
- numbness, seizures or fits
- involuntary muscle movements including muscle spasms
- sweating or trouble in urinating
- sudden life-threatening allergic reaction
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Make sure that you are with someone who can keep you awake by talking to you or gently shaking you every now and then.

The risk of breathing problems is higher if you:

- have an existing lung condition
- have a small physique
- are an elderly patient
- have kidney or liver disease
- are given a high FENPATCH dose
- you have not used opioid pain relief before.

Your doctor will carefully select the most appropriate dose for you.

Nausea, vomiting, diarrhoea, anxiety and shivering may occur initially when you are switched from other opioid analgesics to FENPATCH or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects. Medicines like FENPATCH can lead to addiction. This is unlikely when FENPATCH is used correctly.

Other side effects not listed above, sexual dysfunction and withdrawal symptoms, may also occur in some people. Tell your doctor if you notice any other effects.

After using FENPATCH

Storage

Keep the patches in the sealed pouch until it is time to apply them.

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

Keep used and unused patches where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store FENPATCH or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

The contents of the patches may be retrieved and abused by addicts.

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

If your doctor tells you to stop using FENPATCH, or if the medicine is damaged or is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Product description

What it looks like

FENPATCH patches are rectangular, round-cornered, transparent patches imprinted with:

- 'fentanyl 12µg/h' for the 12 micrograms/hour strength
- 'fentanyl 25µg/h' for the 25 microgram/hour strength
- 'fentanyl 50µg/h' for the 50 microgram/hour strength
- 'fentanyl 75µg/h' for the 75 microgram/hour strength
- 'fentanyl 100µg/h' for the 100 microgram/hour strength

Each pack contains 5 patches. Each patch is in a sealed pouch.

They are available in five sizes. The number after the name FENPATCH refers to the amount of fentanyl in micrograms (one thousandth of a milligram) released by the patch per hour.

Ingredients

The patches contain the active ingredient fentanyl.

The patch is composed of polyacrylate adhesive.

Australian Registration numbers

FENPATCH 12 (AUST R 143880)
 FENPATCH 25 (AUST R 143894)
 FENPATCH 50 (AUST R 143895)
 FENPATCH 75 (AUST R 143904)
 FENPATCH 100 (AUST R 143905)

Supplier

Sponsor

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