DENPAX

Transdermal System

fentanyl

Consumer Medicine Information

WARNING

Limitations of use

DENPAX 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

DENPAX 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

DENPAX 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 DENPAX 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 DENPAX 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 DENPAX.

What is in this leaflet

This leaflet answers some common questions about DENPAX. 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 taking DENPAX against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What DENPAX is used for

DENPAX is used to relieve chronic or long-lasting pain, which requires strong painkillers (when other pain relief treatment has failed).

DENPAX is only used in people who have previously been using other opioid-based pain relief.

DENPAX is not used to treat pain that you only have once in a while.

DENPAX patches contain 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 three days (72 hours). The transdermal patch releases a continuous amount of fentanyl that is absorbed through the skin in contact with the patch.

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

Your doctor may have prescribed DENPAX for another reason.

Warning

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

DENPAX maybe become habit-forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

DENPAX patches may be retrieved and abused by addicts. 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 transdermal patches where children cannot reach them.

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

Tolerance

As with all opioid analgesics, DENPAX may lead to tolerance with continued use. Tolerance means that the effect of the medicine may decrease and more is needed to produce the same effect. Therefore, it is possible your doctor will prescribe a higher dose of DENPAX after some time to produce the same result.

Dependence and withdrawal

As with all other opioids, your body may become used to you taking DENPAX after several days to weeks of continued use resulting in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking DENPAX suddenly. Some examples of withdrawal symptoms include feeling uneasy and unwell, restless, agitated, anxious, increased pain, sweating, chills, weakness, stomach cramps, problems sleeping, nausea, vomiting, diarrhoea, increased blood pressure,

fast breathing and fast heartbeat. DENPAX 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.

Increased sensitivity to pain

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Before you use DENPAX

When you must not use it

Do not use DENPAX if you have an allergy to:

- any medicine containing fentanyl
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You should not use DENPAX:

- if you have or have ever had lung disease
- for acute pain or pain following surgery
- for mild or intermittent pain

at a starting dose greater than 25 micrograms/hour This medication should not be prescribed to patients who have not used opioid analgesics before. Please discuss with your doctor.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

You must tell your doctor if you:

- are pregnant or planning to become pregnant
- are breast feeding or wish to breast feed
- 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 brain lesions 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

You must tell your doctor if you have not used any opioid analgesics in the past. This is because you may be more likely to experience some of the side effects.

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

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

Your doctor will advise you whether to use DENPAX or if you need to adjust the dose or adapt your treatment.

Children

DENPAX 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.

Taking other medicines

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

Tell your doctor or pharmacist if you are taking any of the following:

- other strong analgesics used to manage pain such as opioids and general anaesthetics
- ritonavir or nelfinavir (used to treat AIDS)

  Do not take ritonavir or nelfinavir while using DENPAX, unless you are closely monitored by your doctor.
- rifampicin, carbmazepine, phenobarbital (phenobarbitone) or phenytoin, careful monitoring by your doctor and dose adjustment may be required
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs), selective serotonin re-uptake inhibitors (SSRIs) or serotonin norepinephrine re-uptake inhibitors (SNRIs)

  DENPAX should not be used in combination with these medicines. DENPAX should be initiated 14 days after stopping treatment with MAOIs. Combination of these medicines with DENPAX may increase the risk of serotonin syndrome, a potentially life-threatening condition
- certain medicines to treat depression such as nefazodone
- medicines that slow down your central nervous system (for example medicines that make you sleepy, reduce anxiety or decrease awareness, such as sedatives, hypnotics, sleeping tablets, tranquillisers, strong pain killers (opioids), medicines used for surgery (anaesthetics), muscle relaxants, allergy medicine that makes you drowsy, gabapentinoid medicines used to treat epilepsy or nerve pain such as gabapentin and pregablin, alcohol, cannabis or some illegal drugs)

  Combination of these medicines with DENPAX may increase the sedative effect of these drugs or slow down your ability to react, breathing difficulties with slow or shallow breathing, coma and death. A change in dose by your doctor may be required if DENPAX is used with these medicines
- medicines used to treat mental illness or psychotic conditions and to relieve severe nausea and vomiting, such as phenothiazines
- certain antibiotics used to treat infections such as clarithromycin and troleandomycin
- certain medicines used to treat fungal infections such as ketoconazole and itraconazole
- idelalisib (cancer treatment)
- sedating antihistamines
- certain medicines that act on the heart and blood vessels such as calcium-channel blockers like verapamil and diltiazem
- certain medicines used to treat arrhythmias such as amiodarone

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

Effect of Alcohol

Avoid alcohol when using DENPAX since their combined effects may cause drowsiness, slow down your ability to react, breathing difficulties with slow or shallow breathing, coma and death.

Using DENPAX

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to use the patch

Adults

DENPAX is available in five different sizes. 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 in 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). If you are using more than one patch,

change all your patches at the same time. The old patch should be removed before the new patch is applied.

Children

DENPAX 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. Do not stick a patch on straight after a hot bath or shower
2. Trim any excess hair with scissors. Do not shave the hair 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. To open the pouch, locate the pre-cut notch indicated by the scissors. Make a small cut and fold at the notch. Carefully tear the pouch along the edge and then fully open the pouch by folding it open like a book
4. Remove the DENPAX patch from the sealed pouch

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

5. Each DENPAX patch has a clear plastic protective (release) 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

Avoid touching the adhesive side of the patch

6. Apply the patch to the skin and press with the palm of the hand for about 30 seconds. Make sure the entire patch is in contact with the skin and the corners are stuck tightly
7. Wash your hands after applying or removing the patch

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

If you do have a shower or bath whilst wearing your patch be careful that the water is not too hot and do not soak in a hot bath for a long time.

Always write the date and time you applied the patch on the pack. It will help you to use DENPAX 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. 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
3. Apply a new patch straight away to a different area of the skin, following the steps under "Using DENPAX - Applying the patch"

Make a note of the day, date and time you apply a patch, to remind you when you need to change your patch.

There is enough medicine in each patch to last 3 days (72 hours).

You should change your patch every third day, unless your doctor has told you differently. If the patch comes off before 3 days, a new patch of the same strength should be applied to a new spot of intact skin.

Always change your patch at the same time of day every 3 days (72 hours).

If your pain continues, see your doctor who may prescribe additional medicines to help control the pain or change the dose of DENPAX. Your doctor may advise you initially to change the patch every two days (48 hours) instead of every three days (72 hours) to achieve adequate pain relief.

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)

The most important sign of overdose is difficulty in breathing. If a person using DENPAX has abnormally slow or weak breathing, remove the patch. Keep the person awake by talking to them or gently shaking them every now and then.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have received too much DENPAX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Information for the doctor in case of overdose: inject with naloxone and transfer patient to hospital.

While you are using DENPAX

Things you must do

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are using DENPAX.

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 or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

DENPAX should not be used during childbirth as the medicine can slow the breathing of the newborn child. Prolonged use of DENPAX during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized or treated. If you are breast feeding, you should not use DENPAX since it may be present in your milk.

Tell 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 DENPAX transdermal patch
- you develop a fever

  At high temperatures, the amount of fentanyl absorbed by the skin increases. Your doctor may need to adjust your DENPAX dose

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

Whilst wearing your patch you can go outside in the sun but you must cover the patch with clothing on hot sunny days.

Do not use DENPAX to treat any other complaints unless your doctor says so.

Do not give the patches to anyone else, even if their symptoms seem similar to yours.

Do not stop using DENPAX unless your doctor advises you to do so. If you have been using DENPAX for a long period of time but stop using it suddenly without your doctor's advice, you may experience withdrawal symptoms (such as nausea, vomiting, diarrhoea, anxiety and shivering). Seek your doctor's advice if you experience these symptoms.

Do not cut, break, chew, crush, dissolve, snort or inject DENPAX.

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 contact your doctor. Do this even if there are no signs of discomfort or drowsiness.

DENPAX 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.

Check with your doctor or pharmacist before switching brands.

Side effects

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

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 of the 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 notice any of the following and they worry you:

- nausea, vomiting, constipation, dry mouth, diarrhoea, uncomfortable feeling in the stomach or belching after eating, indigestion, blockage in the bowel
- 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
- numbness; seizures or fits
- involuntary muscle movements including muscle spasms
- sweating or trouble urinating
- stopping breathing from time to time whilst sleeping (sleep apnoea)
- rash, itching or hives on the skin
- 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 heartbeat

- fast heartbeat

REMOVE the DENPAX patch and tell your doctor immediately or go to Accident and Emergency 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 urinating
- sudden life threatening allergic reaction

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

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

Nausea, vomiting, diarrhoea, anxiety and shivering may occur initially when you are switched from other opioid analgesics to DENPAX or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects.

Medicines like DENPAX can lead to addiction. This is unlikely when DENPAX is used correctly.

Other side effects not listed above, such as sexual dysfunction and withdrawal symptoms, may also occur in some people.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using DENPAX

Storage

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

If you take the patches out of the pouch they may not keep well.

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

Store this medicine securely, where other people cannot access it. It may harm people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

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

Heat and dampness can destroy some medicines.

Keep DENPAX 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.

Disposal

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

Fold used patches so that the adhesive side of the patch sticks to itself, then wrap and dispose of carefully. You may return used patches to your pharmacy for disposal if you are unsure.

If your doctor tells you to stop using DENPAX or the patches have passed their expiry date, return the transdermal patches to your pharmacist.

Product description

What it looks like

DENPAX patches are rectangular, transparent patches imprinted with

- "fentanyl 1.28 mg delivers 12 mcg/hr" in white for the 12 micrograms/hour strength
- "fentanyl 2.55 mg delivers 25 mcg/hr" in white for the 25 micrograms/hour strength
- "fentanyl 5.1 mg delivers 50 mcg/hr" in white for the 50 micrograms/hour strength
- "fentanyl 7.65 mg delivers 75 mcg/hr" in white for the 75 micrograms/hour strength
- "fentanyl 10.2 mg delivers 100 mcg/hr" in white for the 100 micrograms/hour strength

Each pack contains five (5) patches.

They are available in five (5) sizes. The number beneath the name DENPAX refers to the amount of fentanyl in micrograms (one thousandth of a milligram) released by the transdermal patch per hour.

Ingredients

The patches contain the active ingredient fentanyl.

The patch is made of a silicon adhesive, dimethicone 360, polyolefin film, white ink and a fluorocarbon-coated polyester release liner.

Manufacturer

DENPAX is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

DENPAX fentanyl transdermal patch 12 micrograms/hour: AUST R 163066

DENPAX fentanyl transdermal patch 25 micrograms/hour: AUST R 163068

DENPAX fentanyl transdermal patch 50 micrograms/hour: AUST R 163064

DENPAX fentanyl transdermal patch 75 micrograms/hour: AUST R 163065

DENPAX fentanyl transdermal patch 100 micrograms/hour: AUST R 163067

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