DUROGESIC®

Transdermal System

Fentanyl

Consumer Medicine Information

WARNING

Limitations of use

DUROGESIC 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

DUROGESIC 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

DUROGESIC 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 DUROGESIC 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 DUROGESIC 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 DUROGESIC.

What is in this leaflet

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

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

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

What DUROGESIC is used for

DUROGESIC 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. DUROGESIC is only used in people who have previously been using other opioid-based pain relief. DUROGESIC is not used to treat pain that you only have once in a while.

DUROGESIC 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 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.

Before you use DUROGESIC

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.

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

DUROGESIC 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 DUROGESIC patches, particularly in children, may result in breathing difficulties, with slow or shallow breathing, that could lead to death. Improper use including DUROGESIC patches sticking to another person can be life-threatening.

DUROGESIC 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, DUROGESIC 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 DUROGESIC after some time to produce the same result.

Dependence and withdrawal

As with all other opioids, your body may become used to you taking DUROGESIC 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 DUROGESIC 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.

DUROGESIC 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.

When you must not use it

Do not use DUROGESIC

- 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 condition or breathing difficulties
- 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.

Do not use DUROGESIC if the packaging is torn or shows signs of tampering. Do not use DUROGESIC 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 problems with your liver or kidney
- 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 problems with your heart
- 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 DUROGESIC.

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 DUROGESIC or if you need to adjust the dose or adapt your treatment.

Children

DUROGESIC 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 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 makes you sleepy, reduce anxiety such as sedatives, hypnotics, sleeping tablets, tranquillisers (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 DUROGESIC may make you even more drowsy, slow down your ability to react, have decrease awareness, breathing difficulties with slow or shallow breathing, coma and death. A change in dose by your doctor may be required if DUROGESIC is used with these medicines.

- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs). DUROGESIC should not be used together with MAOIs as this may cause severe serotonin syndrome which is 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. Do not use DUROGESIC if you have taken an MAOI in the last 14 days.
- 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 DUROGESIC may increase the risk of serotonin syndrome.
- 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 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 DUROGESIC, unless you are closely monitored by your doctor.
- if taking rifampicin, carbamazepine, phenobarbital or phenytoin, careful monitoring by your doctor and dose adjustment may be required.
- Idelalisib (cancer treatment)
- certain medicines that act on the heart and blood vessels such as calcium-channel blockers like verapamil and diltiazem, nicardipine.
- 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 of alcohol

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

Using DUROGESIC

How to use the patch

Adults

DUROGESIC 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.

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.

Using and changing the patches

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 remove the old patch before applying a new one.

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

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.

Where to apply the patch

Apply the patch to non-irritated and non-irradiated skin on a flat surface of the upper body or upper arms.

Do not apply the patch on:

- the same place twice in a row
- areas that you move a lot (joints)
- skin that is red, burnt or damaged
- hairy skin

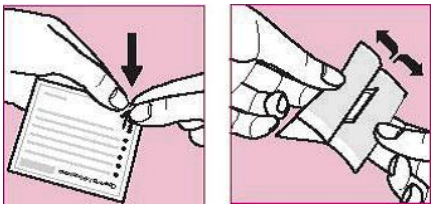
Putting a patch on

Step 1: Preparing the skin

- Hair at the application site (a hairless area is preferable) should be trimmed with scissors (not shaved) prior to application. The skin should be healthy and undamaged. Do not place the patch onto skin that is red, burnt or damaged.
- If the site of DUROGESIC application needs to be cleaned before applying the patch, this should be done with clear water. Do not use soaps, oils, or any other cleaners, creams or moisturisers.
- Make sure your skin is completely dry before the patch is applied. Do not stick a patch on straight after a hot bath or shower. Patches should be inspected prior to use.

Step 2: Open the pouch

- DUROGESIC patch should be applied immediately upon removal from the sealed package.
- To remove the patch from the protective pouch, locate the precut notch (indicated by an arrow on the patch label) along the edge of the seal.
- Fold the pouch at the notch, then carefully tear the pouch material.
- Inspect the patch for any damage. Patches that are cut, divided, or damaged in any way should not be used.
- Further open the pouch along both sides, folding the pouch open like a book.



- The clear plastic protective (release) liner for the patch is slit.
- Fold the patch in the middle and remove each half of the liner separately.

Step 3: Peel and press

- Avoid touching the adhesive side of the patch.
- Apply the patch to the skin by applying light pressure with the palm of the hand for about 30 seconds.
- Make sure the entire patch is in contact with skin, the corners and the edges of the patch are adhering properly.
- Then wash hands with clean water.

Step 4: Disposing of the patch

- As soon as you take a patch off, fold it firmly in half so that the sticky side sticks to itself.
- Put it back in its original sachet and dispose of the sachet as instructed by your pharmacist.
- Unused patches should be returned to the pharmacy.
- **Keep used patches out of sight and reach of children – even used patches contain some medicine which may harm children and may even be fatal.**

Step 5: Wash

- Always wash your hands after you have handled the patch using clean water only.

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

Children

DUROGESIC 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.

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)

Immediately remove the patch(es) and phone triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then.

Also, phone the Poisons Information Centre for advice, or go to the Emergency Department at your nearest hospital if you think you or anyone else may have used too much DUROGESIC.

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

Poisons Information Centre telephone number:

- Australia: 13 11 26

Keep this telephone number handy.

You should also follow the above steps if someone other than you have accidentally used DUROGESIC 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 heart beat
- Nausea or vomiting
- Convulsions or fits

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

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 DUROGESIC

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 DUROGESIC. DUROGESIC should not be used during childbirth as the medicine can slow the breathing of the newborn child. Prolonged use of DUROGESIC 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 DUROGESIC 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 DUROGESIC patch.
- 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 DUROGESIC dose
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using DUROGESIC.

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 DUROGESIC. 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 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 DUROGESIC unless your doctor advises you to do so. If you have been using DUROGESIC 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 DUROGESIC.**

  This can result in serious side effects and death.

Things to be careful of

- If the patch accidentally sticks to another person (for example a family member sharing the same bed) or is accidentally swallowed (for example by a child), remove the patch and phone triple zero (000). Do this even if there are no signs of discomfort or drowsiness.
- DUROGESIC 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 in the bowel, problem 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 heartbeat.
- fast heartbeat.

REMOVE the DUROGESIC patch and phone triple zero (000) 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 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 DUROGESIC 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 DUROGESIC or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects.

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

After using DUROGESIC

Storage

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

Keep the patches in a dry place where temperature stays below 30°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.

Keep your medicines 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 DUROGESIC patches 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 DUROGESIC patches may be retrieved and abused or misused illegally.

Fold used patches so that the adhesive side of the patch sticks to itself, then wrap and dispose of it carefully.

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

Product Description

What it looks like

- DUROGESIC 12 micrograms/ hour patches are rectangular shape with rounded corners, translucent system with printed border and "Durogesic 12 mcg fentanyl/h" in orange ink.
- DUROGESIC 25 micrograms/ hour patches are rectangular shape with rounded corners, translucent system with printed border and "Durogesic 25 mcg fentanyl/h" in red ink.
- DUROGESIC 50 micrograms/ hour patches are rectangular shape with rounded corners, translucent system with printed border and "Durogesic 50 mcg fentanyl/h" in green ink.
- DUROGESIC 75 micrograms/ hour patches are rectangular shape with rounded corners, translucent system with printed border and "Durogesic 75 mcg fentanyl/h" in blue ink.
- DUROGESIC 100 micrograms/ hour patches are rectangular shape with rounded corners, translucent system with printed border and "Durogesic 100 mcg fentanyl/h" in grey ink.

Each pack contains 5 patches.

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

DUROGESIC 12 micrograms/hour (AUST R 116828)

DUROGESIC 25 micrograms/hour (AUST R 112368)

DUROGESIC 50 micrograms/hour (AUST R 112369)

DUROGESIC 75 micrograms/hour (AUST R 112370)

DUROGESIC 100 micrograms/hour (AUST R 112371)

Ingredients

The patches contain the active ingredient fentanyl.

The patch is made of polyethylene terephalate, ethylene/VA copolymer and polyacrylate adhesive Duro-Tak 87-4287.

Sponsor

Janssen-Cilag Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

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