

This leaflet was prepared in March 2011. Please check with your pharmacist if an updated version of this leaflet has been made available

DUROGESIC[®] Transdermal System

Fentanyl

Consumer Medicine Information

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 to relieve chronic or long-lasting pain, which requires strong painkillers.

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

Warning

DUROGESIC 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 patches where children cannot reach them.

Before you use DUROGESIC

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
- other than the 12 micrograms/hour patch if you have never had opioid analgesics for pain relief.

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 liver or kidney disease
- have or have ever had lung disease
- have or have ever had heart disorders
- have or have ever had brain lesions or head injuries
- have medical conditions which lower your resistance to diseases.

You must tell your doctor if you have not used any opioid analgesics in the past, unless you are being treated for cancer pain. This is because you may be more likely to experience some of the side effects.

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.

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

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:

- other strong analgesics used to manage pain such as morphine, codeine, methadone, oxycodone, pethidine or buprenorphine.
- ritonavir and nelfinavir (used to treat AIDS). Do not take ritonavir or nelfinavir while using DUROGESIC, unless you are closely monitored by your doctor.
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs) including moclobemide, phenelzine sulfate and tranylcypromine sulfate. DUROGESIC should not be used concurrently with these medicines and should be initiated 14 days after cessation of MAOIs.
- certain medicines to treat depression such as nefazodone
- medicines used as sedatives, sleeping tablets, tranquillisers or muscle relaxants.
- medicines used to treat mental illness or psychotic conditions and to relieve severe nausea and vomiting.
- certain antibiotics used to treat infections such as clarithromycin and troleandomycin.
- certain medicines to treat fungal infections such as ketoconazole and itraconazole
- medicines used as antihistamines that are sedating.
- 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.

DUROGESIC can increase the effect of drugs that are sedating or slow down your ability to react. A change in dose may be required if DUROGESIC is used with these medicines.

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

Effect on driving and operating machinery

DUROGESIC 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

Avoid alcohol when using DUROGESIC since their combined effect may cause drowsiness.

Tolerance

As with all opioid analgesics, DUROGESIC may lead to tolerance with continued use. Your doctor may, therefore, prescribe a higher dose of DUROGESIC after some time to continue to give you pain relief.

Using DUROGESIC

How to use the patch

Adults

DUROGESIC is available in five different sizes. Your doctor will decide which patch, or combination of patches, is suitable to control your pain.

- 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

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.

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. 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 DUROGESIC 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 DUROGESIC 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 all of the patch is in contact with skin and the corners are stuck tightly.
7. Wash 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.

Always write the date and time you applied the patch on the pack. It will help you to use DUROGESIC 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 **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 DUROGESIC. Your doctor may advise you initially to change the patch every 48 hours instead of every 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 DUROGESIC 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 for advice, or go to the Emergency Department at your nearest hospital.

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

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 764 766 or 0800 POISON

Keep these telephone numbers handy.

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

Please refer to full Product Information for details on appropriate management of overdose.

While you are using DUROGESIC

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while using DUROGESIC.
- 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 use DUROGESIC 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.
- 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 nausea, vomiting, diarrhoea, anxiety and shivering). Seek your doctor's advice if you experience these symptoms.

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.
- 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.
- low blood pressure, headache, weakness or dizziness, high blood pressure.
- sleepiness, confusion, hallucinations, euphoria, depression, loss of appetite, anxiety, trouble sleeping, agitation, loss of memory, pins and needles.
- 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.

- skin rash (local redness and itch at the site of the patch is usually mild and resolves when the patch is removed).
- unusual tiredness or weakness, feeling of body temperature change.

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 DUROGESIC 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.

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 DUROGESIC or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects.

Medicines like DUROGESIC can lead to addiction. This is unlikely when DUROGESIC 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 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.

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.

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

This leaflet was prepared in March 2011.

Disposal

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

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

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 patches are rectangular, transparent patches imprinted with:

- 'Durogesic 12 µg fentanyl/h' in orange for the 12 micrograms/hour strength
- 'Durogesic 25 µg fentanyl/h' in red for the 25 microgram/hour strength
- 'Durogesic 50 µg fentanyl/h' in green for the 50 microgram/hour strength
- 'Durogesic 75 µg fentanyl/h' in blue for the 75 microgram/hour strength
- 'Durogesic 100 µg fentanyl/h' in grey for the 100 microgram/hour strength

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 terephthalate, ethylene/VA copolymer and polyacrylate adhesive Duro-Tak 87-4287.

Sponsor

Janssen-Cilag Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia