PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 6

DUROGESIC® (fentanyl) 12 µg/h transdermal patch

DUROGESIC® (fentanyl) 25 µg/h transdermal patch

DUROGESIC® (fentanyl) 50 µg/h transdermal patch

DUROGESIC® (fentanyl) 75 µg/h transdermal patch

DUROGESIC® (fentanyl) 100 µg/h transdermal patch

Read all of this leaflet carefully before you start using DUROGESIC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse or other health care provider
- DUROGESIC has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

What is in this leaflet

1. What DUROGESIC is and what it is used for.
2. What you need to know before you use DUROGESIC.
3. How to use DUROGESIC.

4. Possible side effects.
5. How to store DUROGESIC.
6. Contents of the pack and other information.

1. What DUROGESIC is and what it is used for

DUROGESIC is indicated in the management of chronic intractable pain that requires opioid analgesia, which cannot be managed by lesser means such as paracetamol – opioid combinations, non-steroidal analgesics or as required dosing with short-acting opioids.

2. What you need to know before you use DUROGESIC

Do not use DUROGESIC

- if you are hypersensitive (allergic) to fentanyl or any of the other ingredients of DUROGESIC (Refer to WHAT DUROGESIC CONTAINS, above.)
- unless your doctor has prescribed it for chronic pain.
- if you are pregnant or breastfeeding.
- in children less than 2 years of age. DUROGESIC should only be used in children ages 2 – 16 years who are already using narcotic pain medicines (opioid tolerant).
- if you are taking medicines as described under the heading “Using other medicines with DUROGESIC”.
- if you are taking monoamine oxidase inhibitors or within 14 days of stopping
- DUROGESIC is not suited for the relief of pain following surgery or short-term pain.

- Do not use DUROGESIC if you have breathing difficulties, with slow or shallow breathing.

Warnings and precautions

Take special care with DUROGESIC:

- 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 death.
- Keep unused and used DUROGESIC patches out of children's reach. A patch may be tempting to a child. Accidental exposure to 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 low levels of oxygen in the blood and a problem called sleep apnea (stopping breathing from time to time whilst sleeping). Tell your doctor if you have a history of sleep apnea or if anyone notices you stop breathing from time to time whilst sleeping
- If you suffer from problems with your lungs, heart, brain, liver, kidneys or have severe constipation, inform your doctor. You may need close medical surveillance while using DUROGESIC.
- If you are using certain medicines for depression known as Serotonin Re-uptake Inhibitors (SSRIs), or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs), inform your doctor.

Other medicines and DUROGESIC

Always tell your healthcare professional if you are taking any other medicines or using alcohol

(This includes complementary or traditional medicines).

DUROGESIC should not be taken with medications that can interfere with the breakdown of the active ingredient, fentanyl. Combination with DUROGESIC requires additional monitoring and/or may require a dose change. Examples of such medicines include:

- certain AIDS medicines such as HIV protease inhibitors, (*such as ritonavir and nelfinavir*);
- certain antibiotics used to treat infections, (*such as clarithromycin, troleandomycin and rifampicin*);
- certain medicines used to treat fungal infections (*such as ketoconazole and itraconazole*);
- certain medicines that act on the heart and blood vessels (such as certain calcium-channel blockers like verapamil and diltiazem);
- certain medicines used to treat dysrhythmias; (*such as amiodarone*);
- certain medicines used to treat depression (*such as nefazodone*);
- certain drugs used to treat convulsions (such as carbamazepine, phenobarbital, and phenytoin);
- Inform your doctor, if you are taking medicines that slow down your central nervous system (for example medicines that make you sleepy, reduce anxiety or decrease awareness such as (sedatives, tranquilisers, sleeping pills, strong pain killer (opioids), medicines used for surgery (anaesthetics), muscle relaxants, allergy medicines that make you drowsy, alcohol or some illegal drugs. You should take them by prescription only since their combined effect may cause severe

drowsiness, decreased awareness, breathing difficulties with slow or shallow breathing, coma and death.

Tell your healthcare provider if you are using certain medicines for depression known as Serotonin Re-uptake Inhibitors (SSRIs), or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs), or Monoamine Oxidase Inhibitors (MAOIs). The prescriber must be aware of any use of these medicines because their combination with DUROGESIC may increase the risk of serotonin syndrome, a potentially life-threatening condition.

Fever/exposure to heat sources

At high temperatures, greater than usual quantities of medicine can be released in your body. If you have a fever, you should always contact your doctor, who may adjust your dose if necessary. Increased release of DUROGESIC can also result from direct exposure to heat sources. You should avoid, for example, heating pads, electric blankets, heated water beds, heat or tanning lamps, intensive sunbathing, hot water bottles, prolonged hot baths, saunas, and hot whirlpool spa baths.

Tolerance

Over time, DUROGESIC may lead to tolerance. Therefore, it is possible your doctor will prescribe a higher dose of DUROGESIC after some time to produce the same result.

Change in the pain you are feeling

Tell your doctor if:

- you feel your pain is no longer relieved by the patch
- you feel an increase in pain

- there is a change in how you feel the pain (for example, you feel pain in another part of your body)
- you feel pain when something touches your body that you wouldn't expect to hurt you.

Do not change the dose yourself. Your doctor may decide to change your dose or treatment.

Damaged patch

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

Do not apply the patch if it looks divided, cut or damaged.

Patch sticking to another person

The patch should be used only on the skin of the person for whom it was ordered by the doctor. A few cases are known where a patch has accidentally stuck to a family member while in close physical contact such as sharing the same bed as the patch wearer. In case the patch sticks to the skin of another person, take the patch off immediately and seek medical attention.

Handling the Patch

DUROGESIC should be applied to non-irritated and non-irradiated skin on a flat surface of the torso or upper arms. In younger children, the upper back is the preferred location to minimise the potential of the child removing the patch. Hair at the application site (a non-hairy area is preferable) should be clipped (not shaved as shaving irritates the skin) prior to application. If the site of DUROGESIC application requires cleansing prior to application of the patch, this should be done with clear water only. Soaps, oils, lotions, or any other agent that might irritate the skin or alter its characteristics should not be

used. Pat dry the skin before the patch is applied. Inspect the patch for any damage. Do not use a patch that has been cut, divided or damaged in any way.

DUROGESIC should be applied immediately upon removal from the sealed package. To remove the patch from the protective pouch, locate the pre-cut 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. Further open the pouch along both sides, folding the pouch open like a book. The release liner for the patch is slit. Fold the patch in the middle and remove each half of the liner separately. 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 certain that the edges of the patch are adhering properly. Then wash hands with clean water.

DUROGESIC may be worn continuously for 72 hours. A new patch should be applied to a different skin site after removal of the previous transdermal patch. Several days should elapse before a new patch is applied to the same area of the skin.

Used patches should be folded so that the adhesive side of the patch adheres to itself and then they should be safely discarded. Unused patches should be returned to the (hospital) pharmacy.

Wash hands, with water only, after applying or removing the patch.

Pregnancy, breastfeeding and fertility

Do not use DUROGESIC during pregnancy and do not breastfeed. (Refer to BEFORE YOU USE DUROGESIC, above).

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.

Driving and using machines

DUROGESIC may affect alertness and driving skills. Therefore, you should not drive a vehicle or operate machinery until your doctor has told you that you may.

3. How to use DUROGESIC

Do not share medicines prescribed for you with any other person.
Always take DUROGESIC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with DUROGESIC will last. Do not stop treatment early because your symptoms (pain) may return. If you have the impression that the effect of DUROGESIC is too strong or too weak, tell your doctor or pharmacist.
Ensure that your doctor is aware that you are using DUROGESIC before any surgical procedure

DUROGESIC comes in the form of adhesive patches to be applied to the skin. It comes in 5 different patches, each with a different size and strength.
You can easily recognise the strength by the figure mentioned after DUROGESIC and the colour of the packet:
DUROGESIC100 µg/h, grey colour;
DUROGESIC 75 µg/h, blue colour;
DUROGESIC 50 µg/h, green colour;
DUROGEDIC 25 µg/h, pink colour,
DUROGESIC 12 µg/h, orange colour.

The figures following the word DUROGESIC refer to the amount of fentanyl in micrograms, (µg, one thousandth of a milligram) released by the patch every hour (h). DUROGESIC100 thus releases the largest quantity of active ingredient, DUROGESIC 12 the smallest.

The strength of patch your doctor prescribes will depend on the severity of your pain, your general condition, and what you have already taken to relieve the pain. Therefore, your doctor will decide which strength of patch or which combination of patches suits your condition best.

Starting with DUROGESIC

Use of DUROGESIC

At the start of DUROGESIC therapy it may take a while before the painkilling effect sets in. This is because the medicine slowly passes through the skin and into your blood. It may take 1 day (24 hours) before DUROGESIC becomes fully effective. Therefore, you might need additional painkillers on the first day of therapy.

If your pain comes back, see your doctor, who may prescribe additional painkillers and adapt the strength and dose of DUROGESIC. Your doctor may also let you use several patches of DUROGESIC at the same time.

Your doctor may prescribe additional painkillers to relieve occasional outbursts of pain.

Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or illegal drugs.

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 follow your doctor's instructions carefully and ask advice before changing or stopping the treatment

Instructions for Use/Handling and Disposal

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.
- 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).
- If you are using more than one patch, change all your patches at the same time.

Where to apply the patch

- Do not apply the patch on the same place twice in a row.
- DUROGESIC should be applied to nonirritated and nonirradiated skin on a flat surface of the torso or upper arms.

Children

- Always apply the patch to the upper back to make it difficult for your child to reach it or take it off.
- Every so often check that the patch remains stuck to the skin.
- It is important that your child does not remove the patch and put it in their mouth as this could be life threatening or even fatal.

- Watch your child very closely for 48 hours after:
  - The first patch has been put on
  - A higher dose patch has been put on
- It may take some time for the patch to have its maximum effect. Therefore, your child might need to use other painkillers as well until the patches become effective. Your doctor will talk to you about this.

Putting a patch on

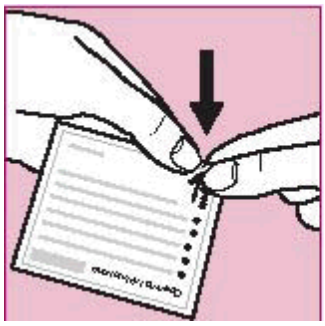
Step 1: Preparing the skin

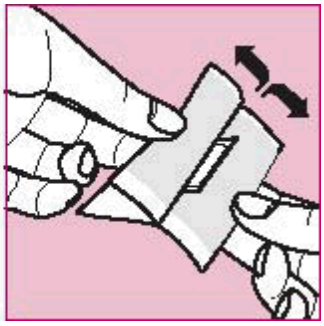
- Hair at the application site (a nonhairy area is preferable) should be clipped (not shaved) prior to application.
- If the site of DUROGESIC application requires cleansing prior to application of the patch, this should be done with clear water. Soaps, oils, lotions, or any other agent that might irritate the skin or alter its characteristics should not be used.
- The skin should be completely dry before the patch is applied. Patches should be inspected prior to use.

Step 2: Open the pouch

- DUROGESIC 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 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 certain that 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 (hospital) 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 use more DUROGESIC than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The most important sign of overdose is suppressed breathing. If a person is breathing abnormally, slowly, or weakly, remove the patch and call your doctor immediately. Meanwhile, keep the person awake by talking to him/her or by shaking him/her every now and then.

Information for the doctor in case of overdose

Inject naloxone and transfer the patient to hospital

If you stop using DUROGESIC

Only your doctor can decide whether you should stop using DUROGESIC. Never stop treatment without your doctor's advice

4. POSSIBLE SIDE EFFECTS

DUROGESIC can have side effects. Not all side effects reported for DUROGESIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DUROGESIC, please consult your doctor, pharmacist or other healthcare professional for advice.

DUROGESIC may make you unusually drowsy and make your breathing more slow or shallow. Very rarely these breathing problems can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers (like DUROGESIC or

morphine) before. If you, or your partner or carer, notice that the person wearing the patch is unusually drowsy, with slow or shallow breathing:

- Take the patch off

- Call a doctor, or go to your nearest hospital straight away

- Keep the person moving and talking as much as possible

Listed below are side effects (also called adverse drug reactions) related to the treatment with DUROGESIC

Frequent:

Headache, dizziness, and sleepiness;

Nausea and vomiting;

Constipation which may be severe.

Loss of appetite;

Confusion; seeing, hearing, smelling, feeling, or tasting things that are not present;

Anxiety; feeling very sad or depressed;

Difficulty in either going to sleep or staying asleep; trembling; tingling sensation;

Awareness of heart beating; fast heart beat;

High blood pressure;

Dry mouth; indigestion, upset stomach; stomach pain; diarrhoea;

Itchy skin; redness of the skin; skin rash; excessive sweating; allergic reaction involving hives;

Involuntary muscle movements including muscle spasms;

Tiredness; weakness; feeling of general discomfort or uneasiness; feeling cold; swelling of the feet, ankles, and hands;

Inability to pass urine;

Shortness of breath.

Less frequent:

A feeling of extreme wellness; agitation;

Numbness; loss of memory; seizures (also called convulsions);

Slow heart beat; bluish colouration of the skin;

Low blood pressure;

Difficult breathing;

Distention of tummy and blockage of the gut (bowel obstruction)

Skin inflammation or skin rash caused by contact with something to which you are allergic;

Difficulty during any stage of normal sexual response (desire, arousal, or orgasm); inability to obtain or maintain an erection;

Reaction at the application site (including allergic reactions); feeling either hot or cold; flu-like illness; unpleasant symptoms that occur after a medicine is stopped or the dose lowered.

Constriction of the pupil;

Not able to breath; too little air entering the lungs.

Allergic reaction severe enough to cause wheezing, difficulty in breathing, and a very low blood pressure that can also be serious or life-threatening;

Very slow breathing rate.

Fever

Blurred vision

Being less alert or aware

Loss of consciousness

Androgen deficiency

Low level of oxygen in the blood

Stopping breathing from time to time whilst sleeping

If you get a fever while using DUROGESIC, tell your doctor - this may increase the amount of medicine that passes through your skin.

• DUROGESIC may cause constipation, talk to your doctor or pharmacist for advice on how to prevent or relieve constipation.

• Repeated, long-term use of the patches may make the medicine less effective (you become 'tolerant' to it) or you may become dependent on it.

See section 4 for a full list of possible side effects.

When you are wearing the patch do not expose it to direct heat such as heating pads, electric blankets, hot-water bottles, heated water beds or heat or tanning lamps. Do not sunbathe, have long hot baths or saunas, or use hot whirlpool spa baths. If you do, you may increase the amount of medicine you get from the patch.

Medicines such as DUROGESIC can lead to habituation. This is highly unlikely when the medicine is used correctly.

If long-term treatment with DUROGESIC is stopped suddenly, withdrawal symptoms such as nausea, vomiting, diarrhoea, anxiety, and shivering may occur. Therefore, never stop your DUROGESIC treatment without talking to your doctor. If your doctor considers it necessary to stop, always follow his or her instructions carefully. Similar undesirable effects may also occur if a switch is made from other opioid painkillers to DUROGESIC. Should you be bothered by any of the above adverse effects, inform your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DUROGESIC.

Alternatively, you may report side effects experienced with DUROGESIC directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5. How to store DUROGESIC

Store all medicines out of the reach of children.

Store DUROGESIC at or below 25 °C (normal room temperature) and make sure that the pouches with the patches are kept well closed and that they are not damaged.

This medicine can be kept for only a limited period. Do not use DUROGESIC after the date (month and year) printed after "EXP", even if it has been stored properly.

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.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

The active substance is fentanyl.

- The adhesive patches also contain other ingredients:

  Backing layer: Polyester*/EVA**

  Medicine layer: Polyacrylate adhesive

  Inks (on backing): Orange /red /green /blue / grey printing ink

  Protective liner: Siliconised polyester

  *Polyester = Polyethylene terephthalate

  **EVA = Ethinyl vinyl acetate

What DUROGESIC looks like and contents of the pack

DUROGESIC patches are rectangular with rounded corners, translucent units comprising a protective liner and two functional layers.

DUROGESIC patches are available in 5 strengths and each patch has a border with its name and strength printed on it in its respective colour

- DUROGESIC 12 µg/h: orange coloured printing
- DUROGESIC 25 µg/h: red coloured printing
- DUROGESIC 50 µg/h: green coloured printing
- DUROGESIC 75 µg/h: blue coloured printing
- DUROGESIC 100 µg/h: grey coloured printing

Each DUROGESIC patch is packed in a flat colour-coded heat-sealed pouch (see IDENTIFICATION) and is supplied in cartons containing 5 pouches.

HOLDER OF CERTIFICATE OF REGISTRATION

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Registration/Application number(s)

DUROGESIC 12 µg/h - A40/2.9/0203

DUROGESIC 25 µg/h - 28/2.9/0288

DUROGESIC 50 µg/h - 28/2.9/0289

DUROGESIC 75 µg/h - 28/2.9/0290

DUROGESIC 100 µg/h - 28/2.9/0291

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.