

## **PATIENT INFORMATION LEAFLET**

### **SCHEDULING STATUS**

Schedule 6

### **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**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 further questions, please ask your doctor or your pharmacist.
- This medicine 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.

### **1. WHAT DUROGESIC CONTAINS**

- The active substance in DUROGESIC is fentanyl. There are 5 different strengths of DUROGESIC: 12 µg/h; 25 µg/h; 50 µg/h; 75 µg/h; 100 µg/h, respectively.
- 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

## 2. WHAT DUROGESIC IS USED FOR

It is used to relieve severe long-lasting pain, which requires morphine-like painkillers.

## 3. 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 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**”

### Take special care with DUROGESIC:

- DUROGESIC is not suited for the relief of pain following surgery.
- Keep unused and used DUROGESIC patches out of children’s reach.
- In conditions such as lung disorders, heart diseases, brain lesions, diminished action of liver or kidneys.
- If you suffer from any of these disorders, 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), or Monoamine Oxidase Inhibitors (MAOIs), inform your doctor.

### Pregnancy and Breastfeeding:

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

### Driving and using machinery:

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.

**Using other medicines with DUROGESIC:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

DUROGESIC should not be taken with medications that can interfere with the breakdown of the active ingredient, fentanyl. The prescriber must be aware of any use of these medicines.

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 and troleandomycin*);
- 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*);
- If you are taking medicines that diminish your reactions (*tranquilisers, sleeping pills, etc.*), inform your doctor. You should take them by prescription only since their combined effect may cause drowsiness.

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

Tell your health care 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.

### **Damaged or leaking 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 must 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 sharing the same bed as the patient. In case the patch sticks to the skin of another person, take the patch off immediately and call a doctor.

### **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 matrix 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.

#### **4. 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.

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;
- DUROGESIC 25 µg/h, red colour,
- and DUROGESIC 12 µg/h, orange colour.

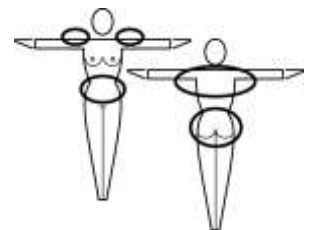
The figures following the word DUROGESIC refer to the amount of fentanyl in micrograms, (µg, one thousandth of a milligram) released by the patch every hour (h). DUROGESIC 100 thus releases the largest quantity of active ingredient, DUROGESIC 12 the smallest.

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**

#### **1. Prepare:**

For adults, put the patch on the chest, back, or upper arm in a place where there is no hair. In young children, put the patch on the upper back to lower the chances of the child removing the patch and putting it in his/her mouth. Put it on right away after you have removed it from the pouch. Clip any hair as close to the skin as possible, **do not shave (shaving irritates the skin)**. Clean the



skin with clear water only. **Pat skin completely dry.** Do not use anything on the skin (soaps, lotions, oils, alcohol, etc.) before the patch is applied.

**2. Peel:**

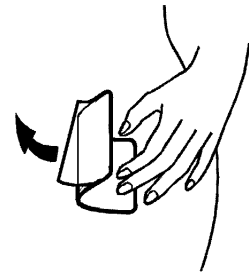
Peel the liner from the back of the patch and throw away.

Touch the sticky side as little as possible.



**3. Press:**

Press the patch onto the skin **with the palm of your hand and hold there for a minimum of 30 seconds.** Make sure it sticks well, especially at the edges.



Leave the patch on for 3 days (72 hours). You may take a bath, a shower or go swimming. Always write down the date you applied a patch. There is room on the box. It will help you use DUROGESIC correctly and to remember when the 3 days are over.

### **Changing a patch of DUROGESIC**

After 3 days, remove the patch by peeling it off.

Immediately fold a used patch in half with the adhesive side facing inward and dispose of safely.

Apply a new patch right away, but never in the same place as the previous one. Pick a new spot of intact skin.

Follow the application instructions under "Starting with DUROGESIC".

### **Stopping with DUROGESIC**

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

### **Useful information**

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.

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

### **If you use more DUROGESIC than you should:**

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

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.

## **5. 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 sometimes slow down breathing. If a person on DUROGESIC is breathing too slowly or weakly, call the doctor immediately. Meanwhile, keep the person awake by talking or shaking him/her every now and then.

The most common undesired effects reported with DUROGESIC use are nausea, vomiting, constipation, sleepiness, headache, dizziness, itching, sweating, and confusion. Other side effects might include slow heart beat, hallucinations, unnatural state of well-being (euphoria), trouble urinating, and redness at the application site. Should any of these undesired effects occur, see your doctor, who will evaluate their severity and tell you what to do.

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.

## **6. STORING AND DISPOSING OF DUROGESIC**

Store all medicines out of 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 it has been stored properly.

Return all unused medicine to your pharmacist.

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

## **7. PRESENTATION OF DUROGESIC**

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

## **8. IDENTIFICATION OF DUROGESIC**

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

## **9. REGISTRATION NUMBER/REFERENCE NUMBER**

12 µg/h - A40/2.9/0203

25 µg/h - 28/2.9/0288

50 µg/h - 28/2.9/0289

75 µg/h - 28/2.9/0290

100 µg/h - 28/2.9/0291

**10. THE NAME BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE  
CERTIFICATE OF REGISTRATION**



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**11. DATE OF PUBLICATION**

• **Date of registration of DUROGESIC range:**

12 µg/h – 15 August 2008

25 µg/h – 09 March 1994

50 µg/h – 06 June 1994

75 µg/h – 30 March 1994

100 µg/h – 30 March 1994

• **Date of most recently revised patient information leaflet as approved by the Advisory**

**Clinical Committee:** 28 May 2018.