

Package leaflet: Information for the user

Durogesic® DTrans® 50 micrograms/hour transdermal patch (fentanyl)

Your medicine is available using the above name but will be referred to as Durogesic DTrans throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you (or your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Durogesic DTrans is and what it is used for
2. What you need to know before you use Durogesic DTrans
3. How to use Durogesic DTrans
4. Possible side effects
5. How to store Durogesic DTrans
6. Contents of the pack and other information

1. What Durogesic DTrans is and what it is used for

The name of your medicine is Durogesic DTrans.

The patches help relieve pain that is very bad and long-lasting:

- in adults who need continuous pain treatment
- in children above 2 years of age who are already using opioid medication and who need continuous pain treatment.

Durogesic DTrans contains a medicine called fentanyl. It belongs to a group of strong painkillers called opioids.

2. What you need to know before you use Durogesic DTrans

Do not use Durogesic DTrans if:

- You are allergic to fentanyl or any of the other ingredients of this medicine (listed in section 6)
- You have pain which lasts only for a short period, such as sudden pain or pain after having an operation
- You have breathing difficulties, with slow or shallow breathing

Do not use this medicine if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before using Durogesic DTrans.

Warnings and precautions

- Durogesic DTrans can have life-threatening side effects in people who are not already regularly using prescribed opioid medicines.
- Durogesic DTrans is a medicine that could be life-threatening to children, even if the patches have been used. Bear in mind that a sticky patch (unused or used) could be tempting to a child and if it sticks to a child's skin or they put it in their mouth, the result may be fatal.

Patch sticking to another person

The patch should be used only on the skin of the person for whom it has been prescribed. There have been reports of patches accidentally sticking to a family member while in close physical contact or sharing the same bed as the person wearing the patch. A patch accidentally sticking to another person (particularly a child) can cause the medicine in the patch to go through the skin of the other person and cause serious side effects such as breathing difficulties, with slow or shallow breathing which may be fatal. In case the patch sticks to the skin of another person, take the patch off right away and get medical attention.

Take special care with Durogesic DTrans

Talk to your doctor or pharmacist before using this medicine if any of the following apply to you - your doctor may need to check you more closely if:

- You have ever had problems with your lungs or breathing
- You have ever had problems with your heart, liver, kidneys, or low blood pressure
- You have ever had a brain tumour
- You have ever had persistent headaches or a head injury
- You are elderly - you may be more sensitive to the effects of this medicine
- You have a condition called 'myasthenia gravis' in which muscles become weak and tire easily
- You have ever abused or been dependent on alcohol, prescription medicines or illegal drugs.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Durogesic DTrans.

Side effects and Durogesic DTrans

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

Other medicines and Durogesic DTrans

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines. You should also tell your pharmacist that you are using Durogesic DTrans if you buy any medicines from your pharmacy.

Your doctor will know which medicines are safe to take with Durogesic DTrans. You may need to be closely monitored if you are taking some of the types of medicines listed below or if you stop taking some of the types of medicines listed below, as this may affect the strength of Durogesic DTrans you need.

In particular, tell your doctor or pharmacist if you are taking:

- Other medicines for pain, such as other opioid painkillers (such as buprenorphine, nalbuphine, or pentazocine).
- Medicines for helping you sleep (such as temazepam, zaleplon, or zolpidem).
- Medicines to help you calm down (tranquillisers, such as alprazolam, clonazepam, diazepam, hydroxyzine, or lorazepam) and medicines for mental conditions (anti-psychotics, such as aripiprazole, haloperidol, olanzapine, risperidone, or phenothiazines).
- Medicines for relaxing your muscles (such as cyclobenzaprine or diazepam).
- Some medicines used to treat depression called SSRIs or SNRIs (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, or venlafaxine). - see below for more information
- Some medicines used to treat depression or Parkinson's disease called MAOIs (such as isocarboxazid, phenelzine, selegiline or tranylcypromine). You should not take Durogesic DTrans within 14 days of stopping these medicines. - see below for more information

- Some antihistamines, especially ones that make you sleepy (such as chlorpheniramine, clemastine, cyproheptadine, diphenhydramine, or hydroxyzine).
- Some antibiotics used to treat infection (such as erythromycin or clarithromycin).
- Medicines used to treat fungal infection (such as itraconazole, ketoconazole, fluconazole, or voriconazole).
- Medicines used to treat HIV infection (such as ritonavir).
- Medicines used to treat an irregular heart beat (such as amiodarone, diltiazem, or verapamil).
- Medicines to treat tuberculosis (such as rifampicin).
- Some medicines used to treat epilepsy (such as carbamazepine, phenobarbital, or phenytoin).
- Some medicines used to treat nausea or motion sickness (such as phenothiazines).
- Some medicines used to treat heartburn or ulcers (such as cimetidine).
- Some medicines used to treat angina (chest pain) or high blood pressure (such as nifedipine).
- Some medicines used to treat cancer of the blood (such as idelalisib).

Durogesic DTrans with antidepressants

The risk of side effects increases if you are taking medicines such as certain antidepressants. Durogesic DTrans may interact with these medicines and you may experience changes to mental status such as feeling agitated, seeing, feeling, hearing, or smelling things that are not there (hallucinations) and other effects such as changing blood pressure, fast heart beat, high body temperature, overactive reflexes, lack of coordination, muscle stiffness, nausea, vomiting and diarrhoea.

Operations

If you think that you are going to receive anaesthesia tell your doctor or dentist that you are using Durogesic DTrans.

Durogesic DTrans and alcohol

Do not drink alcohol while using Durogesic DTrans unless you have talked to your doctor first. Durogesic DTrans can make you drowsy or breathe more slowly. Drinking alcohol may make these effects worse.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Durogesic DTrans should not be used during pregnancy unless you have discussed this with your doctor.

Durogesic DTrans should not be used during childbirth as the medication can affect the breathing of the newborn child.

Do not use Durogesic DTrans if you are breastfeeding. You should not breastfeed for 3 days after removing your Durogesic DTrans patch. This is because the medicine may pass into breast milk.

Driving and using machines

Durogesic DTrans can affect your ability to drive and use machines or tools as it may make you sleepy or dizzy. If this happens, do not drive or use any tools or machines. Do not drive while using this medicine until you know how it affects you.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How to use Durogesic DTrans

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide which strength of Durogesic DTrans is most suitable for you, taking into account the severity of your pain, your general condition and type of pain treatment that you have received so far.

Using and changing the patches

- 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.
- Make a note of the day, date and time you apply a patch, to remind you when you need to change your patch.
- The following table shows you when to change your patch:

Apply your patch on	Change your patch on
Monday	Thursday
Tuesday	Friday
Wednesday	Saturday
Thursday	Sunday
Friday	Monday
Saturday	Tuesday
Sunday	Wednesday

Where to apply the patch

Adults

- Apply the patch on a flat part of your upper body or arm (not over a joint).

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.

Adults and Children:

Do not apply the patch on

- The same place twice in a row.
- Areas that you move a lot (joints), skin that is irritated or with cuts.
- Skin that is very hairy. If there is hair, do not shave it (shaving irritates the skin). Instead, clip the hair as close to the skin as possible.

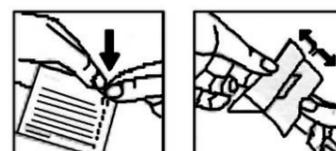
Putting a patch on

Step 1: Preparing the skin

- Make sure your skin is completely dry, clean and cool before you put the patch on
- If you need to clean the skin, just use cold water
- Do not use soap or any other cleansers, creams, moisturisers, oils or talc before applying the patch
- Do not stick a patch on straight after a hot bath or shower

Step 2: Open the sachet

- Each patch is sealed in its own sachet
- Tear or cut open the sachet at the notch, shown by the arrow
- Gently tear or cut off the edge of the sachet completely (if you use scissors, cut close to the sealed edge of the sachet to avoid damaging the patch)



- Grasp both sides of the opened sachet and pull apart
- Take the patch out and use straight away
- Keep the empty sachet to dispose of the used patch later
- Use each patch once only
- Do not take the patch out of its sachet until you are ready to use it
- Inspect the patch for any damage
- Do not use the patch if it has been divided, cut or looks damaged
- Never divide or cut the patch

Step 3: Peel and press

- Make sure that the patch will be covered by loose clothing and not stuck under a tight or elasticated band
- Carefully peel one half of the shiny plastic backing away from the centre of the patch. Try not to touch the sticky side of the patch
- Press this sticky part of the patch onto the skin
- Remove the other part of the backing and press the whole patch onto the skin with the palm of your hand
- Hold for at least 30 seconds. Make sure it sticks well, especially the edges

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
- 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

More about using Durogesic DTrans

Everyday activities while using the patches

- The patches are waterproof
- You can shower or bathe while wearing a patch, but do not scrub the patch itself
- If your doctor agrees, you can exercise or play sport while wearing the patch
- You can also swim while wearing the patch, but:
 - Don't use hot whirlpool spa baths
 - Don't put a tight or elasticated band over the patch
- While you are wearing the patch do not expose it to direct heat such as heating pads, electric blankets, hot-water bottles, heated water beds, heat or tanning lamps. Do not sunbathe, have long hot baths or saunas. If you do, you may increase the amount of medicine you get from the patch.

How quickly will the patches work?

- It may take some time for your first patch to have its maximum effect
- Your doctor may give you other painkillers as well for the first day or so
- After this, the patch should help to relieve pain continuously so that you can stop taking other painkillers. However, your doctor may still prescribe extra painkillers from time to time

How long will you use the patches for?

- Durogesic DTrans patches are for long-term pain. Your doctor will be able to tell you how long you can expect to use the patches

If your pain gets worse

- If your pain gets worse while you are using these patches, your doctor may try a higher strength patch, or give you additional painkillers (or both)
- If increasing the strength of the patch does not help, your doctor may decide to stop the use of the patches

If you use too many patches or the wrong strength patch

If you have stuck on too many patches or the wrong strength patch, take the patches off and contact a doctor straight away.

Signs of overdose include trouble breathing or shallow breathing, tiredness, extreme sleepiness, being unable to think clearly, walk or talk normally and feeling faint, dizzy or confused.

If you forget to change your patch

- If you forget, change your patch as soon as you remember and make note of the day and time. Change the patch again after **3 days (72 hours)** as usual.
- If you are very late changing your patch, you should talk to your doctor because you might need some extra painkillers, but do **not** apply an extra patch.

If a patch falls off

- If a patch falls off before it needs changing, stick a new one on straight away and make note of the day and time. Use a new area of skin on:
 - Your upper body or arm
 - Your child's upper back
- Let your doctor know this has happened and leave the patch on for another **3 days (72 hours)** or as directed by your doctor, before changing the new patch as usual
- If your patches keep falling off, talk to your doctor, pharmacist or nurse

If you want to stop using the patches

- Talk to your doctor before you stop using these patches
- If you have been using them for some time your body may have got used to them. Stopping suddenly may make you feel unwell
- If you stop using the patches, don't start again without asking your doctor first. You might need a different patch strength when you restart

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you or your partner, or carer, notice any of the following about the person wearing the patch, take the patch off and call a doctor, or go to your nearest hospital, straight away. You may need urgent medical treatment.

- Feeling unusually drowsy, breathing that is more slow or shallow than expected. Follow the advice above and keep the person who was wearing the patch moving and talking as much as possible. Very rarely these breathing difficulties can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers (like Durogesic DTrans or morphine) before. (Uncommon, this may affect up to 1 in 100 people.)
- Sudden swelling of the face or throat, severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction. (frequency cannot be estimated from the available data.)
- Fits (seizures). (Uncommon, this may affect up to 1 in 100 people.)
- Reduced consciousness or loss of consciousness. (Uncommon, these may affect up to 1 in 100 people.)

The following side effects have also been reported

Very common (may affect more than 1 in 10 people)

- Nausea, vomiting, constipation
- Feeling sleepy (somnolence)
- Feeling dizzy
- Headache

Common (may affect up to 1 in 10 people)

- Allergic reaction
- Loss of appetite
- Difficulty sleeping
- Depression
- Feeling anxious or confused
- Seeing, feeling, hearing, or smelling things that are not there (hallucinations)
- Muscle tremors or spasms
- Unusual feeling in the skin, such as tingling or crawling feelings (paraesthesia)
- Spinning sensation (vertigo)
- Heart beat feels fast or uneven (palpitations, tachycardia)
- High blood pressure
- Being short of breath (dyspnoea)
- Diarrhoea
- Dry mouth
- Stomach pain or indigestion

- Excessive sweating
- Itching, skin rash or redness of the skin
- Being unable to pass urine or empty bladder completely
- Feeling very tired, weak or generally unwell
- Feeling cold
- Swollen hands, ankles or feet (peripheral oedema)

Uncommon (may affect up to 1 in 100 people)

- Feeling agitated or disoriented
- Feeling extremely happy (euphoria)
- Decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- Loss of memory
- Blurred vision
- Slow heart beat (bradycardia) or low blood pressure
- Blue colour to the skin caused by low oxygen in the blood (cyanosis)
- Loss of contractions of the gut (ileus)
- Itchy skin rash (eczema), allergic reaction or other skin disorders where the patch is placed
- Flu-like illness
- Feeling of body temperature change
- Fever
- Muscle twitching
- Difficulty getting and keeping an erection (impotence) or problems having sex

Rare side effects (may affect up to 1 in 1000 people)

- Constricted pupils (miosis)
- Stopping breathing from time to time (apnoea)

You may notice rashes, redness or slight itching of the skin at the site of the patch. This is usually mild and disappears after you have removed the patch. If it does not, or if the patch irritates your skin badly, tell your doctor.

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

If you switch from a different painkiller to Durogesic DTrans, or if you suddenly stop using Durogesic DTrans, you may notice withdrawal effects such as sickness, feeling sick, diarrhoea, anxiety or shivering. Tell your doctor if you notice any of these effects.

There have been reports also of newborn infants experiencing withdrawal effects after their mothers have used Durogesic DTrans for a long time during pregnancy.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971 Fax: +353 1 6762517

Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store Durogesic DTrans

Where you should keep the patches

Keep all patches (used and unused) out of the sight and reach of children.

This medicinal product does not require any other special storage conditions.

How long to keep Durogesic DTrans for

Do not use this medicine after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month. If the patches are out of date, take them to your pharmacy.

How to dispose of used patches or patches you no longer use

A used or unused patch accidentally sticking to another person, especially a child, may be fatal.

Used patches should be folded firmly in half so that the sticky side of the patch sticks to itself. Then they should be safely discarded by putting them back into the original sachet and stored out of sight and reach of other people, especially children, until safely disposed. Ask your pharmacist how to throw away medicines you no longer use.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Durogesic DTrans contains

The active substance in Durogesic DTrans Patch is fentanyl. Each transdermal patch contains 8.4 milligrams of fentanyl (absorption rate approx 50 micrograms/hour: active surface area 21.0cm²).

The other ingredients in the patch are: polyacrylate adhesive, polyethylene terephthalate/ethyl vinyl acetate film, green printing ink and siliconised polyester film.

What Durogesic DTrans looks like and contents of the pack

Durogesic DTrans is a translucent, rectangular patch with rounded corners, marked with the product name, strength and a border in green coloured ink.

Each patch is marked

Durogesic®

50 µg fentanyl/h

The patch has a sticky back so that it can be stuck onto the skin.

The Durogesic DTrans Patch usually come in cartons containing five Durogesic DTrans patches, but your doctor will have prescribed the number and strength of Durogesic DTrans Patch which is best for you.

Manufacturer

Manufactured by: Janssen-Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA1151/252/001

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The leaflet revision date is: 21.12.17

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Hungary, Iceland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovenia, Sweden	Durogesic
Germany	Durogesic SMAT
Ireland, Malta, United Kingdom	Durogesic DTrans
Spain	Durogesic Matrix

Blind or partially sighted?

Is this leaflet hard to see or read?

Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:

Product name: Durogesic DTrans 50 micrograms/hour transdermal patch

Reference No: PPA1151/252/001