

PACKAGE LEAFLET: INFORMATION FOR THE USER

Durogesic® DTrans®  
25 micrograms/hour Transdermal Patch  
50 micrograms/hour Transdermal Patch  
75 micrograms/hour Transdermal Patch  
100 micrograms/hour Transdermal Patch  
(fentanyl)

Your medicine is available using the above names but will be referred to as ‘Durogesic DTrans patch’ or just ‘patch’ throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, nurse or pharmacist
- This medicine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist

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1. WHAT DUROGESIC DTRANS PATCHES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Durogesic DTrans transdermal patch. It is called ‘Durogesic DTrans patch’ or just ‘patch’ in this leaflet.

Durogesic DTrans patch contains a medicine called fentanyl. It belongs to a group of strong painkillers called opioids. The patches come in five strengths (see section 6 overleaf). The medicine passes slowly into your body through your skin.

What Durogesic DTrans patches are used for

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

2. BEFORE YOU USE DUROGESIC DTRANS PATCHES

Durogesic DTrans patches can be used in children aged 2 to 16 years who have previously used opioid painkillers. If the patches have been prescribed for your child, the ‘you’ stated everywhere below should be read as ‘your child’.

Do not use Durogesic DTrans patches if:

- You are allergic to fentanyl, Durogesic or anything in Durogesic DTrans patches (listed in section 6 overleaf)
- You have pain which begins suddenly and lasts only for a short period, or after you have had surgery or an injury
- You have breathing problems, from a lung disease or severe asthma. Symptoms may include breathlessness and coughing
- Your child who is in pain is under two years old
- Your child has not been treated with strong painkillers such as morphine

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

Take special care with Durogesic DTrans patches

- Check with your doctor or pharmacist before using this medicine if you have ever had:
  - Problems with your heart or blood pressure, liver or kidneys
  - Brain tumours
  - Persistent headaches or a head injuryYour doctor might need to check you more closely.
- If you are very ill, very thin or elderly, you may be more sensitive to the effects of the patches
- If you suffer from a condition in which muscles become weak and tire easily, known as myasthenia gravis, talk to your doctor or pharmacist before using Durogesic DTrans patches.
- **If you develop a fever while wearing Durogesic DTrans patches, tell your doctor as this may affect the way the medicine passes through your skin**
- **Don’t expose the patch to direct heat such as heating pads, hot-water bottles, electric blankets, heated water beds, heat or tanning lamps, intensive sun bathing, long hot baths, saunas or hot whirlpool spa baths. These may affect the way the medicine is absorbed through the skin**
- Like some other strong painkillers, Durogesic DTrans patches may make you unusually drowsy, and breathe more slowly or weakly. Very rarely these breathing difficulties can be life-threatening or even fatal in people who have not used strong opioid painkillers (like Durogesic DTrans or morphine) before. If you, or your partner or carer, notice that you or your child are breathing much more slowly or weakly:
  - Take the patch off
  - Call a doctor, or go to your nearest hospital, straight away
  - Keep moving and talking as much as possible
- Like many other strong painkillers, repeated use of the patches may make you become tolerant to the medicine or become dependent on it
- Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs
- Durogesic DTrans may cause constipation, talk to your doctor or pharmacist for advice on how to prevent constipation
- If you develop severe pain in the stomach with swollen stomach, you are unable to pass wind or a bowel motion and feel sick or are being sick, call a doctor straight away
- Check with your doctor or pharmacist before using this medicine if you are taking or have recently taken certain medicines for depression called Selective Serotonin Re-uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) or Monoamine oxidase inhibitors (MAOIs), as they may increase the risk of a condition called serotonin syndrome. (See section 4 for the signs and symptoms of serotonin syndrome. Also see section ‘Taking other medicines’)

If you are not sure if any of the above applies to you or your child, talk to your doctor or pharmacist before using Durogesic DTrans patches.

Other makes of patch

There are other makes of fentanyl transdermal patch available, but they are not all the same. If your patch looks different from one you have used before, you should check with your doctor or pharmacist before using it.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 patches if you buy any medicines from your pharmacy.

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

- Other medicines for pain, such as other opioid painkillers (buprenorphine, nalbuphine or pentazocine)
- Medicines for helping you sleep
- Medicines to help you calm down (tranquillisers) and medicines for mental conditions
- Medicines for relaxing your muscles
- Some medicines used to treat depression ‘monoamine oxidase inhibitors’ (MAOIs) (such as isocarboxid, moclobemide, phenelzine, tranylcypromine). You should not take Durogesic DTrans within 14 days of stopping these medicines. See section ‘Take special care with Durogesic DTrans patches’
- Some medicines used to treat depression called Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). See section ‘Take special care with Durogesic DTrans patches’
- Nefazodone a medicine used to treat depression
- Some antihistamines (especially ones that make you sleepy)
- Some antibiotics used to treat infection, such as erythromycin, clarithromycin or troleandomycin
- Medicines used to treat fungal infection, such as itraconazole, ketoconazole, fluconazole or voriconazole

- Medicines used to treat HIV infection, such as ritonavir or nelfinavir
  - Medicines used to treat an irregular heart beat, such as amiodarone, diltiazem or verapamil
  - Rifampicin (for treatment of TB)
  - Some medicines used to treat epilepsy (such as carbamazepine, phenobarbital or phenytoin)
- Your doctor will know which medicines are safe to take with Durogesic DTrans patches. You may need to be closely monitored if you are taking some of the types of medicines listed above or if you stop taking some of the types of medicines listed above, as this may affect the strength of Durogesic DTrans you need. If you are not sure if any of the above applies to you or your child, talk to your doctor or pharmacist before using Durogesic DTrans patches.

Operations or tests

If you think that you are going to have an anaesthetic, tell your doctor or dentist that you are using Durogesic DTrans.

Using Durogesic DTrans patches and drinking alcohol

Do not drink alcohol while using the patches unless you have talked to your doctor first.

Durogesic DTrans patches can make you drowsy or breathe more slowly. Drinking alcohol may make these effects worse.

See also “Take special care with Durogesic DTrans patches” above.

Pregnancy and breast-feeding

You must tell your doctor before using Durogesic DTrans patches if you (or your daughter who is using the patches) are pregnant, think you may be pregnant or might become pregnant, as they may affect the unborn child.

Durogesic DTrans patches should not be used during childbirth as they can affect your unborn child.

Do not use Durogesic DTrans patches if you are breast-feeding. You should not breast-feed for 3 days after removing your Durogesic DTrans patch. This is because small amounts of the medicine may pass into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Durogesic DTrans patches can make you drowsy. If this happens, do not drive or use any tools or machines.

3. HOW TO USE DUROGESIC DTRANS PATCHES

Always use this medicine exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

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 change your patch **at the same time of day**
- If you are using more than one patch, change all your patches at the same time
- Write down the date and time you apply a patch next to the day on the table below
- The following table shows you when to change your patch:

Apply your patch on			Change your patch at the same time on	
Day	Date	Time		
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

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
- It may take 24 hours before the patch becomes fully effective. Therefore, your child might need additional painkillers on the first day of therapy. Your doctor will advise you
- Children should be monitored very closely for 48 hours after:
  - The first patch has been put on
  - A higher dose patch has been put on

For you or your child, **do not apply the patch on**

- The same place twice in a row
- Sensitive areas that you move a lot, skin with cuts, spots or other skin blemishes
- 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

**You should allow several days to pass before you put a new patch on the same area of skin.**

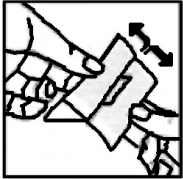
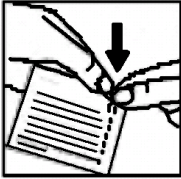
Putting a patch on

Step 1: Preparing the skin

- Make sure the 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 pouch

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



- Grasp both sides of the opened pouch and pull apart
- Take the patch out and use straight away
- Keep the empty pouch to dispose of the used patch later
- Use each patch once only
- Do not take the patch out of its pouch 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 pouch and dispose of in a safe manner
- Even used patches contain some medicine which may harm children, so keep your used patches out of the reach and sight of children

Step 5: Wash

- Wash your hands afterwards with clean water only

More about using Durogesic DTrans patches

How quickly will the patches work?

- It may take up to a day before your first patch is working completely
- Your doctor may give you extra painkillers 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

If you forget to change your patch

- If you forget, change your patch as soon as you remember and make a 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 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 or the nearest hospital 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 a patch falls off

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

If a patch sticks to another person

- Only use the patch on the skin of the person who it was prescribed for
- Make sure the patch does not get rubbed off and stuck to your partner or child, especially while sharing a bed or in close physical contact
- If a patch accidentally sticks to another person, take it off straight away and talk to a doctor

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 the pain gets worse

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

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

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Durogesic DTrans patches can cause side effects, although not everybody gets them.

Take the patch off and tell your doctor, or go to your nearest hospital, straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Feeling unusually drowsy, breathing more slowly or weakly than expected.  
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. If you, or your partner or carer, notice that you or your child are breathing much more slowly or weakly, follow the guidance above and keep moving and talking as much as possible
- Sudden swelling of the face or throat, severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction. This only happens in a small number of people
- Convulsions, fits or seizures. This affects less than 1 in 100 people.

The following side effects have also been reported

Very common (affects more than 1 in 10 people):

- Feeling sick (nausea) or being sick (vomiting), constipation
- Dizziness, drowsiness
- Headache

Common (affects less than 1 in 10 people):

- Allergic reaction
- Awareness of unusual heart beats (also called palpitations), fast heart rate
- High blood pressure
- Loss of appetite or dry mouth
- Feeling nervous, worried or depressed, not being able to sleep
- Confusion, hallucinations (seeing, feeling or hearing things that are not there)
- Sensation of pins and needles, shaking, feeling giddy
- Muscle spasms
- Stomach ache, indigestion, difficulty passing urine
- Diarrhoea
- Feeling cold, excessive sweating
- General feelings of discomfort, tiredness, weakness
- Swelling of hands, ankles or feet
- Itchy skin, rashes or redness of the skin

Uncommon (affects less than 1 in 100 people):

- Flu-like symptoms
- Slow heart rate
- Low blood pressure
- Decreased feeling of sensitivity, especially in the skin
- Bluish colouration of the skin
- Feeling agitated, disorientated, excited or unusually carefree
- Loss of memory
- Eczema and/or other skin disorders including dermatitis where the patch is placed
- Disorders of sexual function
- Complete obstruction of the intestine
- Muscle twitching
- Fever, body temperature changes
- Drug withdrawal effects (such as sickness, feeling sick, diarrhoea, anxiety or shivering)

Rare side effects (probably affecting less than 1 in 1,000 people):

- Tiny pupils
- Incomplete obstruction of the small or large intestine

The following side effects have been reported during clinical trials in children (up to 18 years of age):

Very common side effects (probably affecting more than 1 in 10 people):

- Headache
- Feeling or being sick
- Constipation, diarrhoea
- Itching

Common side effects (probably affecting up to 1 in 10 people):

- Allergic reaction
- Loss of appetite, stomach pain
- Not being able to sleep, drowsiness, tiredness, feeling weak

- Feeling worried or depressed, hallucinations (seeing, feeling or hearing things that are not there), dizziness,
- Shaking, decreased feeling or sensitivity, especially in the skin
- Dry mouth
- Rash, excessive sweating, redness of the skin
- Muscle spasms
- Difficulty passing urine
- Swelling of hands, ankles or feet
- Skin reactions where the patch is placed

Uncommon side effects (probably affecting less than 1 in 100 people):

- Confusion
- Sensation of pins and needles
- Tiny pupils
- Feeling giddy
- Bluish colouration of the skin, eczema and/or other skin disorders including dermatitis where the patch is placed
- Drug withdrawal effects (such as sickness, feeling sick, diarrhoea, anxiety or shivering), flu-like symptoms.

Skin rashes. 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.

Using Durogesic DTrans patches together with certain medicines for depression called Selective Serotonin Re-uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) or Monoamine oxidase inhibitors (MAOIs)

The risk of serotonin syndrome may be increased when Durogesic DTrans patches are used together with some antidepressant medicines (see section ‘Taking other medicines’)

Serotonin syndrome may include:

- Increase in heart rate
- Seeing things that aren’t there (hallucinations)
- Fever, shivering and sweating
- Muscle twitching, jerking and stiffness
- Feeling agitated or confused
- Feeling sick or being sick
- Diarrhoea

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

Like many other strong painkillers, repeated use of the patches may make you become tolerant to the medicine or become dependent on it.

If you get any of these side effects, tell your doctor, nurse or pharmacist.

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

If any of the side effects gets serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. HOW TO STORE DUROGESIC DTRANS PATCHES

How long to keep Durogesic DTrans patches for

Do not use Durogesic DTrans patches after the expiry date which is stated on the carton and pouch. The expiry date (EXP) refers to the last day of that month. If the patches are out of date, take them to your pharmacy.

If your doctor has told you that you or your child no longer need to use the patches, take any unused patches to your pharmacy.

If your Durogesic DTrans Patch appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

The active substance in Durogesic DTrans patches is fentanyl.

The patches come in 4 different strengths (see table below).

Name of patch	Each patch contains:	Each patch gives a dose of:	Active surface area of each patch is:
Durogesic DTrans 25 micrograms/hour Transdermal Patch	4.2mg fentanyl	25mcg per hour	10.5cm <sup>2</sup>
Durogesic DTrans 50 micrograms/hour Transdermal Patch	8.4mg fentanyl	50mcg per hour	21cm <sup>2</sup>
Durogesic DTrans 75 micrograms/hour Transdermal Patch	12.6mg fentanyl	75mcg per hour	31.5cm <sup>2</sup>
Durogesic DTrans 100 micrograms/hour Transdermal Patch	16.8mg fentanyl	100mcg per hour	42cm <sup>2</sup>

The other ingredients are polyacrylate adhesive, polyethylene terephthalate/ethyl vinyl acetate film and siliconised polyester film.

Each patch is identified using a different colour of printing ink:

- Durogesic DTrans 25 micrograms/hour Transdermal Patch is red and will be marked with Fentanyl® 25 µg fentanyl/h
- Durogesic DTrans 50 micrograms/hour Transdermal Patch is green and will be marked with Fentanyl® 50 µg fentanyl/h
- Durogesic DTrans 75 micrograms/hour Transdermal Patch is blue and will be marked with Fentanyl® 75 µg fentanyl/h
- Durogesic DTrans 100 micrograms/hour Transdermal Patch is grey and will be marked with Fentanyl® 100 µg fentanyl/h

What Durogesic DTrans patches look like and contents of the pack

Durogesic DTrans is a transdermal patch. It is a rectangular shaped, clear patch with a sticky back so that it can be stuck onto the skin.

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

Manufacturer

Durogesic DTrans patches are made by: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

Procured from within the EU by the PPA holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

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