

DUTRAN Transdermal Drug Delivery System

contains the active ingredient fentanyl

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DUTRAN. 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 DUTRAN against the benefits this medicine is expected to have for you.

If you have any concerns about using DUTRAN, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What DUTRAN is used for

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

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

Warning

DUTRAN 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 DUTRAN

When you must not use it

Do not use DUTRAN

- 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
- at a starting dose greater than 25 micrograms/hour if you have never had opioid analgesics for pain relief.

Do not use DUTRAN if the packaging is torn or shows signs of tampering. Do not use DUTRAN 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 DUTRAN. 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 DUTRAN 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 opioids and general anaesthetics.
- ritonavir and nelfinavir (used to treat AIDS). Do not take ritonavir or nelfinavir while using DUTRAN, unless you are closely monitored by your doctor.
- if taking rifampicin, carbamazepine, phenobarbital, phenytoin, careful monitoring by your doctor and dose adjustment may be required.
- antidepressant medicines belonging to the class monoamine oxidase inhibitors (MAOIs), selective serotonin re-uptake inhibitors (SSRIs), or serotonin norepinephrine re-uptake inhibitors (SNRIs). DUTRAN should not be used concurrently with these medicines and should be initiated 14 days after cessation of MAOIs. Combination of these medicines with DUTRAN may increase the risk of serotonin syndrome, a potentially life-threatening condition.
- certain medicines to treat depression such as nefazodone.
- sedating antihistamines.
- medicines used as sedatives, hypnotics, sleeping tablets, tranquillisers or muscle relaxants.
Combination of these medicines with DUTRAN may increase the sedative effect of these drugs or slow your ability to react. A change in dose may be required if DUTRAN is used with these medicines.
- medicines used to treat mental illness or psychotic conditions and to relieve severe nausea and vomiting, such as phenothiazines.

- certain antibiotics used to treat infections such as clarithromycin and troleandomycin.
- certain medicines to treat fungal infections such as ketoconazole and itraconazole
- 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.

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

Effect on driving and operating machinery

DUTRAN 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 DUTRAN since their combined effect may cause drowsiness.

Tolerance

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

Using DUTRAN

How to use the patch

Adults

DUTRAN 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

DUTRAN 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. DUTRAN should be applied immediately upon removal from the protective pouch. After locating the tear mark at the edge of the pouch, it should be carefully torn open and the patch removed.
4. Each DUTRAN has a clear plastic protective 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.
Patients should avoid touching the adhesive side of the patch.

- The patch must be applied to the skin by applying light pressure with the palm of the hand for about 30 seconds, making certain the edges are adhering properly.
- Patients should wash hands afterwards with clean water.

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

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 DUTRAN 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

- After three days (72 hours), remove the patch.
- 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.
- 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 DUTRAN.

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 DUTRAN 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 (telephone 13 11 26) 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.

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 DUTRAN

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant while using DUTRAN.
- 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 DUTRAN.
- 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 DUTRAN dose.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using DUTRAN.

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 DUTRAN. 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 DUTRAN 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 DUTRAN unless your doctor advises you to do so. If you have been using DUTRAN 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 of the bowel.
- low blood pressure, headache, weakness or dizziness, high blood pressure, being less alert or aware, or loss of consciousness.
- blurred vision.
- 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 DUTRAN 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 DUTRAN or if therapy is stopped suddenly. Tell your doctor if you experience any of these effects. Medicines like DUTRAN can lead to addiction. This is unlikely when DUTRAN 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 DUTRAN

Storage

Keep the patches in the sealed pouch until it is time to apply them.

Keep the patches in a dry place where temperature stays below 25°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 DUTRAN 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.

Disposal

The contents of the 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 DUTRAN, or the patches have passed their expiry date, return the patches to your pharmacist.

Product description

What it looks like

DUTRAN patches are rectangular, round-cornered, transparent patches imprinted with:

- 'fentanyl 12µg/h' for the 12 micrograms/hour strength
- 'fentanyl 25µg/h' for the 25 microgram/hour strength
- 'fentanyl 50µg/h' for the 50 microgram/hour strength
- 'fentanyl 75µg/h' for the 75 microgram/hour strength
- 'fentanyl 100µg/h' for the 100 microgram/hour strength

Each pack contains 5 patches. Each patch is in a sealed pouch.

They are available in five sizes. The number after the name DUTRAN refers to the amount of fentanyl in micrograms (one thousandth of a milligram) released by the patch per hour.

Ingredients

The patches contain the active ingredient fentanyl.

The patch is composed of polyacrylate adhesive.

Australian Registration numbers

DUTRAN 12 (AUST R 192231)

DUTRAN 25 (AUST R 190790)

DUTRAN 50 (AUST R 190791)

DUTRAN 75 (AUST R 190792)

DUTRAN 100 (AUST R 190793)

Supplier

Amneal Pharma Australia Pty Ltd
12 River St
South Yarra VIC 3141

This leaflet was prepared in October
2017