

Package leaflet: Information for the user

/.../ 12 micrograms/h transdermal patch

fentanyl

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

1. What /.../ is and what it is used for

The name of your medicine is /.../

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.

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

2. What you need to know before you use /.../

Do not use /.../ if:

- You are allergic to fentanyl, soya, peanut 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 /.../.

Warnings and precautions

- | |
|---|
| <ul style="list-style-type: none">• /.../ can have life-threatening side-effects in people who are not already regularly using prescribed opioid medicines. |
|---|

- /.../ 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 /.../

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.
- You have a chronic constipation.

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

Side effects and /.../

- /.../ 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 /.../ 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 /.../, tell your doctor - this may increase the amount of medicine that passes through your skin
- /.../ 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.
- Respiratory depression may persist beyond the removal of the /.../ patch.

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.

Children

/.../ should not be used in children aged less than 2 years because the safety and efficacy have not been established.

/.../ should only be used in children above 2 years of age who are already using opioid medication.

Other medicines and /.../

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 /.../ if you buy any medicines from your pharmacy.

Your doctor will know which medicines are safe to take with /.../. 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 /.../ 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 /.../ 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 nicardipine).
- Some medicines used to treat cancer of the blood (such as idelalisib).

Concomitant use of /.../ and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe /.../ together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

/.../ with antidepressants

The risk of side effects increases if you are taking medicines such as certain antidepressants. /.../ 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 /.../.

/.../ with alcohol

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

/.../ 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 using this medicine.

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

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

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

Driving and using machines

/.../ 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.

/.../ contains soya oil

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to use /.../

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

Your doctor will decide which strength of /.../ 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
- Irradiated skin
- 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

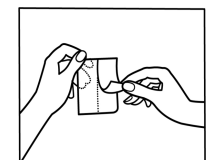
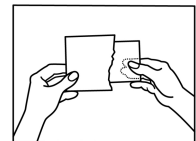
Putting a patch on

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

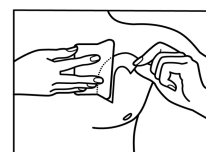
Step 2: Open the sachet

- Each patch is sealed in its own sachet
- Advice for opening child resistant sachet: You'll find a mark which shows you how to cut the sachet (using scissors!), cut close to the sealed edge of the sachet to avoid damaging the patch)
- Rip the sachet alongside using the resulting cuts
- Open the sachet, 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

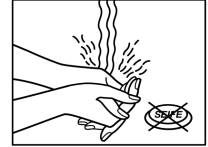


Step 4: Disposing of the patch

- 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 /.../

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?

- /.../ 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 traces of the patch remain on the skin after its removal, these can be cleaned off using copious amounts of soap and water. No alcohol or other solvents may be used for cleaning, as these may penetrate the skin due to the effect of the patch.

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 /.../ 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)

Not known (frequency cannot be estimated from the available data)

- Lack of male sex hormones (androgen deficiency)
- Delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)

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 /.../ or if you suddenly stop using /.../ 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 /.../ 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 *<to be completed nationally>*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../

Where you should keep the patches

Keep all patches (used and unused) out of the sight and reach of children. High quantities of the drug remain in the transdermal patches even after use.

How long to keep /.../ for

Do not use /.../ after the expiry date which is stated on the package. The expiry date refers to the last date 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 /.../ contains

The active substance is fentanyl.

Each patch releases 12.5 micrograms fentanyl per hour. Each patch of 4.25 cm² contains 2.55 mg fentanyl.

The other ingredients are:

Matrix components: Aloe vera leaf extract oil (on the basis of soya oil tocopherol acetate), pentaerythriol esters of hydrogenated colophony, poly(2-ethylhexylacrylate, vinylacetate) (50:50)

Release liner: Polyethylene terephthalate, polyester, siliconized

Backing foil with imprint: polyethylene terephthalate foil, blue printing colour

What /.../ looks like and contents of the pack

/.../ is an opaque, rectangular shaped patch with round corners with a sticky back so that it can be stuck onto the skin. The transdermal patches have the imprint 'Fentanyl 12 µg/h' on the backing foil.

Each transdermal patch is packed individually into sealed child resistant pouch.

/.../ is available in packs of 5, 10, 16 or 20 transdermal patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address }

<{tel}>

<{fax}>

<{e-mail}>

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

This leaflet was last revised in 2019-07-08