



Product:	Tilotrans 25mg, 50mg 75mg and 100mg patches
Item Code:	P3200T
Size:	148 x 675mm
Min. Point size:	8pt
O. Artwork	28/01/25
Proof No.	2
Amendment Date	29/01/25

Colours Used	
	Process Black
	Keyline - does not print

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Tilotrans 25 microgram/hour transdermal patches  
Tilotrans 50 microgram/hour transdermal patches  
Tilotrans 75 microgram/hour transdermal patches  
Tilotrans 100 microgram/hour transdermal patches  
Fentanyl**

**This medicine contains fentanyl which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**Important things you need to know about Tilotrans transdermal patches**

- These patches contain a strong painkiller
- Ensure that old patches are removed before applying a new one
- Patches must not be cut
- Do not expose the patches to a heat source (such as a hot water bottle, electric blankets, heating pads, sunbathe, saunas)
- If you experience a fever tell your doctor immediately
- Follow the dosage instructions carefully and only change your patch every **3 days (72 hours)**
- If your breathing becomes shallow and weak take the patch off and seek medical help.

**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**

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| <b>1</b> What Tilotrans Patch is and what it is used for      | <b>4</b> Possible side effects                      |
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**1 What Tilotrans Patch is and what it is used for**

The full name of this medicine is Tilotrans 25, 50, 75 and 100 microgram/hour transdermal patches but within the leaflet it will be referred to as Tilotrans Patch. Tilotrans Patch contains an active substance called fentanyl. It belongs to a group of **strong painkillers** called opioids.

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.

**2 What you need to know before you use Tilotrans Patch**

**Do not use Tilotrans Patch 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 or pain after having an operation because of the increased risk of dependence and developing serious breathing problems.
- 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 Tilotrans Patch.

**Warnings and precautions**

- Tilotrans Patch can have life-threatening side effects in people who are not already regularly using prescribed opioid medicines.
- Tilotrans Patch is a medicinal product 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.
- Store this medicine in a safe and secure place, where other people cannot access it - see section 5 for more information.

**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 Tilotrans Patch**

**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.

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

**While using the patch, tell your doctor if you have breathing problems while sleeping.**

Opioids like Tilotrans Patch can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxaemia (low oxygen level in the blood). Tell your doctor if you, your partner or carer notice you have any of the following:

- breathing pauses during sleep
- night awakening due to shortness of breath
- difficulties staying asleep
- excessive drowsiness during the day.

Your doctor may decide to change your dose.

**While using the patch, tell your doctor if you notice a change in the pain you are feeling.**

If you feel:

- your pain is no longer relieved by the patch
- an increase in pain
- there is a change in how you feel the pain (for example, you feel pain in another part of your body)
- pain when something touches your body that you wouldn't expect to hurt you.

Do not change the dose yourself. Your doctor may decide to change your dose or treatment.

**Side effects and Tilotrans Patch**

- Tilotrans Patch 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 Tilotrans Patch 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 develop a fever while using Tilotrans Patch tell your doctor - this may increase the amount of medicine that passes through your skin.
- Tilotrans Patch may cause constipation, talk to your doctor or pharmacist for advice on how to prevent or relieve constipation.

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.

**Withdrawal symptoms when stopping Tilotrans Patch**

Do not suddenly stop taking this medicine. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating may occur. If you want to stop taking this medicine, talk to your doctor first. Your doctor will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum.

**Other medicines and Tilotrans Patch**

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 Tilotrans Patch if you buy any medicines from your pharmacy.

Your doctor will know which medicines are safe to take with Tilotrans Patch. 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 Tilotrans Patch 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) and some painkillers for nerve pain (gabapentin and pregabalin).
- 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 Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin-Norepinephrine Reuptake Inhibitors (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 Monoamine Oxidase Inhibitors (MAOIs) such as isocarboxazid, phenelzine, selegiline or

tranylcypromine. You should not take Tilotrans Patch 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).

**Tilotrans Patch with antidepressants**

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

Tilotrans Patch 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. (these could be signs of Serotonin Syndrome). If used together, your doctor may want to closely monitor you for such side effects in particular when starting treatment or when the dose of your medicine is changed.

**Use with central nervous system depressants, including alcohol and some narcotic drugs**

Concomitant use of Tilotrans Patch 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 Tilotrans Patch 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.

Do not drink alcohol during while using Tilotrans Patch unless you have talked to your doctor first.

**Operations**

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

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are currently treated with Tilotrans transdermal patch to discuss your pain management.

**Pregnancy and breast-feeding**

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

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

Tilotrans Patch should not be used during childbirth as the medicine can affect the breathing of the newborn child.

Prolonged use of Tilotrans Patch during pregnancy can cause withdrawal symptoms (such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea) in your newborn baby that could be life-threatening if not recognised and treated. Talk to your doctor immediately if you think your baby may have withdrawal symptoms. Do **not** use Tilotrans Patch if you are breast-feeding. You should not breast-feed for 3 days after removing your Tilotrans Patch. This is because the medicine may pass into breast milk.

**Driving and using machines**

Tilotrans Patch 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.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o It was not affecting your ability to drive safely.

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

**Long-term use and tolerance**

This medicine contains fentanyl which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as drug tolerance). You may also become more sensitive to pain while using Tilotrans Patch. This is known as hyperalgesia. Increasing the dose of your patches may help to further reduce your pain for a while, but it may also be harmful. If you notice that your medicine becomes less effective, talk to your doctor. Your doctor will decide whether it is better for you to increase the dose or to gradually decrease your use of Tilotrans Patch.

**Dependence and addiction**

***This medicine contains fentanyl, which is an opioid. It can cause dependence and/or addiction.***

Repeated use of Tilotrans Patch can also lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to use or how often you need to use it. You might feel that you need to carry on using your medicine, even when it doesn't help to relieve your pain. The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Tilotrans Patch if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illness.

If you notice any of the following signs whilst using Tilotrans Patch, it could be a sign that you have become dependent or addicted.

- You need to use the medicine for longer than advised by your doctor
- You need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once using the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely.

**3 How to use Tilotrans Patch**

Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using Tilotrans Patch, when and how long you need to take it, when to

*continued...*

contact your doctor, and when you need to stop it (see also section 2, withdrawal symptoms when stopping Tilotrans Patch).

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 Tilotrans Patch 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).

##### Use in 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 clean, dry 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
- 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 Tilotrans Patches

##### 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 no 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?

- Tilotrans Patch is 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 suddenly gets worse after placing of your last patch, you should check your patch. If it is no longer sticking well or has fallen off, you should replace the patch (See also section 4 if a patch falls off)
- If your pain gets worse over time 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 an 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. An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

##### 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 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.
- 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 patch keeps falling off, talk to your doctor, nurse or pharmacist.

##### If you want to stop using the patches

- Do not suddenly stop taking this medicine.
- If you want to stop taking this medicine, talk to your doctor first. Your doctor will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. See also section 2 'Withdrawal symptoms when stopping Tilotrans Patch'.
- 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

**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 Tilotrans Patch 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, this 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)

- Heart beat feels, fast or uneven (palpitations, tachycardia)
- Muscle tremors or spasms
- Unusual feeling in the skin, such as tingling or crawling feelings (paraesthesia)
- Being short of breath (dyspnoea)
- Diarrhoea
- Dry mouth
- Loss of appetite
- Stomach pain or indigestion
- Being unable to pass urine or empty bladder completely
- Excessive sweating
- Feeling cold
- Itching skin, rash or redness of the skin
- High blood pressure
- Feeling very tired, weak or generally unwell
- Swollen hands, ankles or feet (peripheral oedema)
- Allergic reaction
- Feeling anxious or confused
- Depression
- Difficulty sleeping
- Seeing, feeling, smelling or hearing things that are not there (hallucinations)
- "Spinning" sensation (vertigo).

##### Uncommon (may affect up to 1 in 100 people)

- Slow heart rate (bradycardia) or low blood pressure
- Blue colour to the skin caused by low oxygen in the blood (cyanosis)
- Decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- Blurred vision
- Muscle twitching
- Loss of memory
- 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
- Fever
- Feeling of body temperature change
- Feeling agitated or disoriented
- Feeling extremely happy (euphoria)
- Difficulty getting and keeping an erection (impotence) or problems having sex
- Difficulty in swallowing.

##### Rare side effects (may affect up to 1 in 1,000 people)

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

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

- Dependence-You can become dependent on Tilotrans Patch (see section 2).

#### The following side effects have also been reported, but their exact frequency is unknown:

- 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 can make the medicine become less effective (you get used to it or you may become more sensitive to pain) or you may become dependent on it.

If you switch from a different painkiller to Tilotrans Patch or if you suddenly stop using Tilotrans Patch, 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 Tilotrans Patch 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 the internet at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Tilotrans Patch

#### Where you should keep the patches

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

Store in the original pouch in order to protect from light. This medicine does not require any special temperature storage conditions.

Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

#### How long to keep Tilotrans Patch 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 date of that month. If the patches are out of date, take them to your pharmacy.

If your doctor has told you that you no longer need to use the patches, take any unused patches 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 Tilotrans Patch contains

Tilotrans 25 microgram/hour transdermal patches  
The active substance is fentanyl.

Each transdermal patch contains: 2.5 mg fentanyl, which delivers a dose of 25 micrograms/hour of fentanyl.

Tilotrans 50 microgram/hour transdermal patches  
The active substance is fentanyl.

Each transdermal patch contains: 5 mg fentanyl, which delivers a dose of 50 micrograms/hour of fentanyl.

Tilotrans 75 microgram/hour transdermal patches  
The active substance is fentanyl.

Each transdermal patch contains: 7.5 mg fentanyl, which delivers a dose of 75 micrograms/hour of fentanyl.

Tilotrans 100 microgram/hour transdermal patches  
The active substance is fentanyl.

Each transdermal patch contains: 10 mg fentanyl, which delivers a dose of 100 micrograms/hour of fentanyl.

#### Other ingredients in the patch are:

Outer membrane: polyethylene-terephthalate/ethylvinylacetate-copolymer.

Medicinal product container: ethanol 96%, hydroxyethylcellulose, purified water.

Control membrane: ethylvinylacetate-copolymer.

Adhesive membrane: silicon medical adhesive.

Protective membrane: (removed before the patch is stuck onto the skin) polyethylene-terephthalate, release coated.

#### What Tilotrans Patches looks like and contents of the pack

Tilotrans Patch is a transparent and oblong transdermal patch packed in a sachet consisting of a protective membrane (removed before the patch is stuck onto the skin), and four functional layers: an outer membrane, a medicinal product container, a control membrane and an adhesive membrane. With the adhesive membrane Tilotrans Patch can be stuck onto the skin.

Tilotrans 25 microgram/hour transdermal patches  
Each transdermal patch is 10 cm<sup>2</sup>, and is marked with a border and "Tilotrans 25 microgram/hour transdermal patches (Fentanyl)" in purple.

Tilotrans 50 microgram/hour transdermal patches  
Each transdermal patch is 20 cm<sup>2</sup>, and is marked with a border and "Tilotrans 50 microgram/hour transdermal patches (Fentanyl)" in blue.

Tilotrans 75 microgram/hour transdermal patches  
Each transdermal patch is 30 cm<sup>2</sup>, and is marked with a border and "Tilotrans 75 microgram/hour transdermal patches (Fentanyl)" in green.

Tilotrans 100 microgram/hour transdermal patches  
Each transdermal patch is 40 cm<sup>2</sup>, and is marked with a border and "Tilotrans 100 microgram/hour transdermal patches (Fentanyl)" in orange.

Tilotrans Patch is available in packs with 3, 5, 7, 10, 14 and 20 transdermal patches.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder:

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

##### Manufacturer:

Hexal AG, Industriestrasse 25, D-83607 Holzkirchen, Germany.

**This leaflet was last revised in January 2025.**