**PACKAGE LEAFLET: INFORMATION FOR THE USER**

# Fentanyl Luye 12 micrograms/hour transdermal patch
# Fentanyl Luye 25 micrograms/hour transdermal patch
# Fentanyl Luye 50 micrograms/hour transdermal patch
# Fentanyl Luye 75 micrograms/hour transdermal patch
# Fentanyl Luye 100 micrograms/hour transdermal patch

fentanyl

## Important things you need to know about Fentanyl Luye transdermal patches

- These patches contain a strong pain killer
- 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)
- If you develop 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 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 Fentanyl Luye is and what it is used for
2. What you need to know before you use Fentanyl Luye
3. How to use Fentanyl Luye
4. Possible side effects
5. How to store Fentanyl Luye
6. Contents of the pack and other information

## 1. What Fentanyl Luye is and what it is used for

The name of your medicine is Fentanyl Luye.
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.

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

## 2. What you need to know before you use Fentanyl Luye

**Do not use Fentanyl Luye 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 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

**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 Fentanyl Luye transdermal patch to discuss your pain management.**

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 Fentanyl Luye.

**Warnings and precautions**

- Fentanyl Luye can have life-threatening side effects in people who are not already regularly using prescribed opioid medicines.
- Fentanyl Luye 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.
- 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 accidently 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 Fentanyl Luye**

**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 Fentanyl Luye.

**While using the patch, tell your doctor if you have breathing problems while sleeping.** Opioids like Fentanyl Luye 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 Fentanyl Luye**
- Fentanyl Luye 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 Fentanyl Luye 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 Fentanyl Luye, tell your doctor - this may increase the amount of medicine that passes through your skin.
- Fentanyl Luye 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.

Fentanyl Luye, like other opioids, may affect the normal production of hormones in the body such as cortisol, prolactin, or sex hormones, particularly if you have taken Fentanyl Luye for long periods of time. The effects of these hormonal changes may include feeling or being sick (including vomiting), loss of appetite, tiredness, weakness, dizziness, low blood pressure, infertility, or decreased sex drive. In addition, female patients may experience changes in menstrual cycle, while male patients may experience impotence or enlarged breasts. If you notice any of these signs, speak to your doctor.

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.

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 Fentanyl Luye. 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 Fentanyl Luye.

Dependence and addiction

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

Repeated use of Fentanyl Luye 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 Fentanyl Luye 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 Fentanyl Luye, 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.

**Withdrawal symptoms when stopping Fentanyl Luye**
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 Fentanyl Luye**
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 Fentanyl Luye if you buy any medicines from your pharmacy.

Your doctor will know which medicines are safe to take with Fentanyl Luye. 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 Fentanyl Luye 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 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 Fentanyl Luye 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).

**Fentanyl Luye with antidepressants**
The risk of side effects increases if you are taking medicines such as certain antidepressants. Fentanyl Luye 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 Fentanyl Luye 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 Fentanyl Luye 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 while using Fentanyl Luye unless you have talked to your doctor first.

**Operations**
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 Fentanyl Luye transdermal patch to discuss your pain management.

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

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

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

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

**Driving and using machines**
Fentanyl Luye 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 taking 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:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - 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.

**Fentanyl Luye contains soya oil**
If you are allergic to soya or peanut, do not use this medicinal product.

## 3. How to use Fentanyl Luye

Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using Fentanyl Luye, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2 “Withdrawal symptoms when stopping Fentanyl Luye”).

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 Fentanyl Luye is most suitable for you, taking into account the severity of your pain, your general condition and type of pain treatment that you have received so far.

**Using and changing the patches**
- There is enough medicine in each patch to last **3 days (72 hours).**
- You should change your patch every third day, unless your doctor has told you differently.
- Always **remove** the old **patch** before applying a **new one**.
- Always change your patch at the same time of day every **3 days (72 hours)**.
- If you are using more than one patch, change all your patches at the same time.
- Make a note of the **day, date** and **time** you apply a patch, to remind you when you need to change your patch.
- The following table shows you when to change your patch:

| **Apply your patch on** | | **Change your patch on** |
|---|---|---|
| Monday | ⇨ | Thursday |
| Tuesday | ⇨ | Friday |
| Wednesday | ⇨ | Saturday |
| Thursday | ⇨ | Sunday |
| Friday | ⇨ | Monday |
| Saturday | ⇨ | Tuesday |
| Sunday | ⇨ | Wednesday |

**Where to apply the patch**
**Adults**

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

**Children**

- Always apply the patch to the upper back to make it difficult for your child to reach it or take it off.
- Every so often check that the patch remains stuck to the skin.
- It is important that your child does not remove the patch and put it in their mouth as this could be life-threatening or even fatal.
- Watch your child very closely for 48 hours after:
  - The first patch has been put on
  - A higher dose patch has been put on
- It may take some time for the patch to have its maximum effect. Therefore, your child might need to use other painkillers as well until the patches become effective. Your doctor will talk to you about this.

**Adults and Children:**

**Do not apply the patch on**

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

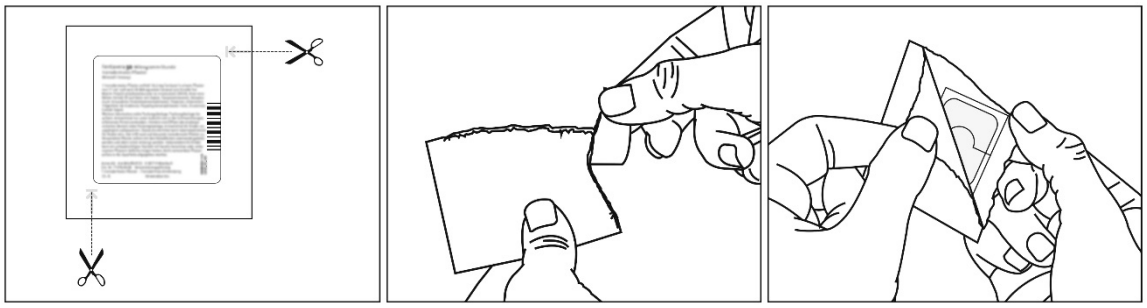
**Putting a patch on**

**Step 1: Preparing the skin**

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

**Step 2: Open the sachet**

- Each patch is sealed in its own sachet
- Tear or cut open the sachet at the notches, as indicated by the arrows
- Gently tear or cut off both edges 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 that 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 Fentanyl Luye**

**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?**
- Fentanyl Luye 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 suddenly gets worse after placing 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 *“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 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 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**
- 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 Fentanyl Luye"*
- If you stop using the patches, don't start again without asking your doctor first. You might need a different patch strength when you restart

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

## 4. Possible side effects

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

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

- Feeling unusually drowsy, breathing that is more slow or shallow than expected.
  Follow the advice above and keep the person who was wearing the patch moving and talking as much as possible. Very rarely these breathing difficulties can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers (like Fentanyl Luye 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 (hypoaesthesia)
- 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
- 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)

**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 can become dependent on Fentanyl Luye (see section 2*)*.

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 can become dependent on it.

If you switch from a different painkiller to Fentanyl Luye or if you suddenly stop using Fentanyl Luye 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 Fentanyl Luye 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 Yellow Card Scheme at: 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 Fentanyl Luye

**Where you should keep the patches**
Keep all patches (used and unused) out of the sight and reach of children.
Store in the original sachet in order to protect from light. This medicinal product does not require any special 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 Fentanyl Luye for**
Do not use Fentanyl Luye 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 Fentanyl Luye contains**
The active substance is fentanyl.

Fentanyl Luye 12 micrograms/hour:
1 transdermal patch contains 2.55 mg fentanyl in a patch size of 4.25 $cm^2$ and releases 12.5 micrograms fentanyl per hour.

Fentanyl Luye 25 micrograms/hour:
1 transdermal patch contains 5.1 mg fentanyl in a patch size of 8.5 $cm^2$ and releases 25 micrograms fentanyl per hour.

Fentanyl Luye 50 micrograms/hour:
1 transdermal patch contains 10.2 mg fentanyl in a patch size of 17 $cm^2$ and releases 50 micrograms fentanyl per hour.

Fentanyl Luye 75 micrograms/hour:
1 transdermal patch contains 15.3 mg fentanyl in a patch size of 25.5 $cm^2$ and releases 75 micrograms fentanyl per hour.

Fentanyl Luye 100 micrograms/hour:
1 transdermal patch contains 20.4 mg fentanyl in a patch size of 34 $cm^2$ and releases 100 micrograms fentanyl per hour.

**Other ingredients in the patch are:**
*Matrix components:* Aloe vera leaf extract oil (on the basis of soya oil tocopherol acetate), colophonium resin, poly(2-ethylhexylacrylate, vinylacetate) (50:50)
*Release liner:* polyethylene terephtalate, polyester, siliconized
*Backing foil with imprint:* polyethylene terephthalate foil, printing ink

**What Fentanyl Luye looks like and contents of the pack**

Fentanyl Luye 12 micrograms/hour:
Fentanyl Luye is an opaque, colourless, rectangular shaped patch with rounded corners and imprint on the backing foil “Fentanyl 12µg/h”.

Fentanyl Luye 25 micrograms/hour:
Fentanyl Luye is an opaque, colourless, rectangular shaped patch with rounded corners and imprint on the backing foil: “Fentanyl 25µg/h”.

Fentanyl Luye 50 micrograms/hour:
Fentanyl Luye is an opaque, colourless, rectangular shaped patch with rounded corners and imprint on the backing foil: “Fentanyl 50µg/h”.

Fentanyl Luye 75 micrograms/hour:
Fentanyl Luye is an opaque, colourless, rectangular shaped patch with rounded corners and imprint on the backing foil: “Fentanyl 75µg/h”.

Fentanyl Luye 100 micrograms/hour:
Fentanyl Luye is an opaque, colourless, rectangular shaped patch with rounded corners and imprint on the backing foil: “Fentanyl 100µg/h”.

The patches come in individually wrapped sealed sachets and come in carton containing 5, 10 or 20 transdermal patches.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**
Luye Pharma Ltd.
40 Occam Road
Guildford, GU2 7YG

**Manufacturer:**
Luye Pharma AG
Am Windfeld 35
83714 Miesbach
Germany

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