



Package leaflet: Information for the user

Fentanyl Zentiva

- 12 micrograms/hour transdermal patch
- 25 micrograms/hour transdermal patch
- 50 micrograms/hour transdermal patch
- 75 micrograms/hour transdermal patch
- 100 micrograms/hour transdermal patch

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

Important things you should know about Fentanyl Zentiva transdermal patches:

- Do not use if you have not been prescribed an opioid medicine before.
- 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).
- Do not soak in a hot bath or take a hot shower whilst wearing a patch.
- If you experience a fever tell your prescriber immediately.
- Follow the dosage instructions carefully and only change your patch at the same time of day every 3 days (72 hours).
- If you feel you need to replace your patch before 72 hours speak to your prescriber, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it.
- 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 Zentiva is and what it is used for
2. What you need to know before you use Fentanyl Zentiva
3. How to use Fentanyl Zentiva
4. Possible side effects
5. How to store Fentanyl Zentiva
6. Contents of the pack and other information

1. What Fentanyl Zentiva is and what it is used for

The name of your medicine is Fentanyl Zentiva.

This medicine has been prescribed for you for relieving 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.

It contains fentanyl which belongs to a group of strong painkillers called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you use Fentanyl Zentiva

Fentanyl is a strong opioid and should not be used unless you have previously been prescribed other opioids.

Do not use Fentanyl Zentiva 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 Fentanyl Zentiva.

Warnings and precautions

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

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to use more Fentanyl Zentiva patches to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Using this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop using this medicine. Withdrawal symptoms can include 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. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop using the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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 immediately and seek medical attention.

Take special care with Fentanyl Zentiva

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 Zentiva.

While using the patch, tell your doctor if you have breathing problems while sleeping. Opioids like Fentanyl Zentiva 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 Zentiva

- Fentanyl Zentiva 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 Zentiva 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 Zentiva, tell your doctor - this may increase the amount of medicine that passes through your skin
- Fentanyl Zentiva 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 Zentiva, 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 Zentiva 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 Zentiva. 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 Zentiva.

Dependence and addiction

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

Repeated use of Fentanyl Zentiva 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 Zentiva 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 Zentiva, 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 Zentiva

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 Zentiva

Tell your doctor or pharmacist if you are taking or 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 Zentiva if you buy any medicines from your pharmacy.

Your doctor will know which medicines are safe to take with Fentanyl Zentiva. 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 Zentiva 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, 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 use Fentanyl Zentiva 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 heartbeat (such as amiodarone, diltiazem or verapamil).
- Medicines used 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 Zentiva with antidepressants

The risk of side effects increases if you are taking medicines such as certain antidepressants. Fentanyl Zentiva 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 heartbeat, 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 Zentiva 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 Zentiva 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 Zentiva 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 Zentiva transdermal patches to discuss your pain management.

Pregnancy and breast-feeding

Do not use Fentanyl Zentiva if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Fentanyl Zentiva during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not use Fentanyl Zentiva while you are breastfeeding as fentanyl passes into breast milk and will affect your baby.

Driving and using machines

- Fentanyl Zentiva 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 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.

3. How to use Fentanyl Zentiva

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

Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using Fentanyl Zentiva, when and how long



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you need to use it, when to contact your doctor, and when you need to stop it (see also section 2 'Withdrawal symptoms when stopping Fentanyl Zentiva').

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 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
- Tear or cut open the sachet at the notch, shown by the arrow
- 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
- Remove the shiny plastic backing, which covers the printed side of the patch
- Carefully peel off one corner of the patch from the shiny plastic backing which covers the sticky side of the patch. Try not to touch the sticky side of the patch
- Press this sticky part of the 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 Zentiva 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 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 Zentiva 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 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 '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 a note of the day and time. Use a new area of the 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 using this medicine. If you want to stop using this medicine, discuss this with your doctor first. They 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 Zentiva'.
- 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 Zentiva 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)

- Feeling sleepy (somnolence)
- Nausea, vomiting, constipation
- Feeling dizzy
- Headache

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- Feeling agitated or disorientated
- Feeling extremely happy (euphoria)
- Flu-like illness
- Slow heart beat (bradycardia) or low blood pressure
- Decreased feeling of sensitivity, especially in the skin (hypoesthesia)
- Blue colour to the skin caused by low oxygen in the blood (cyanosis)
- Loss of memory
- Itchy skin rash (eczema), allergic reaction or other skin disorders where the patch is placed
- Difficulty getting and keeping an erection (impotence) or problems having sex
- Loss of contractions of the gut (ileus)
- Muscle twitching
- Feeling of body temperature change
- Fever
- Blurred vision
- Difficulty 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:

- You can become dependent on Fentanyl Zentiva (see section 2).
- 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 can become dependent on it.

Drug Withdrawal

When you stop using Fentanyl Zentiva, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst using Fentanyl Zentiva, it could be a sign that you have become addicted.

- You need to use the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop using the medicine you feel unwell, and you feel better once using the medicine again

If you notice any of these signs, it is important you talk to your doctor

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 Zentiva

Where you should keep the patches

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

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 Zentiva for

Do not use Fentanyl Zentiva after the expiry date, which is stated on the carton and sachet. The expiry date refers to the last day of that month. If the patches are out of date, take them to your pharmacy.

Do not store above 25°C.

Store in the original sachet in order to protect from moisture.

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 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 Zentiva contains

- The active substance is: fentanyl.
- Each Fentanyl Zentiva 12 micrograms/hour transdermal patch contains 1.375 mg of fentanyl in a patch size of 5 cm², releasing 12.5 micrograms of fentanyl per hour.

Each Fentanyl Zentiva 25 micrograms/hour transdermal patch contains 2.75 mg of fentanyl in a patch size of 10 cm², releasing 25 micrograms of fentanyl per hour.

Each Fentanyl Zentiva 50 micrograms/hour transdermal patch contains 5.5 mg of fentanyl in a patch size of 20 cm², releasing 50 micrograms of fentanyl per hour.

Each Fentanyl Zentiva 75 micrograms/hour transdermal patch contains 8.25 mg of fentanyl in a patch size of 30 cm², releasing 75 micrograms of fentanyl per hour.

Each Fentanyl Zentiva 100 micrograms/hour transdermal patch contains 11.0 mg of fentanyl in a patch size of 40 cm², releasing 100 micrograms of fentanyl per hour.

- The other ingredients are:
 - Overlay liner
 - Polyethylene terephthalate film with fluorocarbon release coating.

Backing Layer
Pigmented polyethylene terephthalate/ethylene vinyl acetate copolymer film

Drug adhesive Layer
Silicone adhesive (dimethicone, silicate resin)
Dimethicone

Rate controlling membrane
Ethylene vinyl acetate copolymer film

Skin adhesive Layer
Silicone adhesive (dimethicone, silicate resin)
Dimethicone

Protective liner
Polyethylene terephthalate film with fluorocarbon release coating

Printing inks
Beige and orange or red or green or blue or grey

What Fentanyl Zentiva looks like and contents of the pack

Fentanyl Zentiva transdermal patch is rectangular with rounded corners, printed on its backing with:

- beige diagonal stripes with repetitive "Fentanyl" in orange font alternating with orange diagonal stripes with repetitive "12 µg/h" in beige font or
- beige diagonal stripes with repetitive "Fentanyl" in red font alternating with red diagonal stripes with repetitive "25 µg/h" in beige font or
- beige diagonal stripes with repetitive "Fentanyl" in green font alternating with green diagonal stripes with repetitive "50 µg/h" in beige font or
- beige diagonal stripes with repetitive "Fentanyl" in blue font alternating with blue diagonal stripes with repetitive "75 µg/h" in beige font or
- beige diagonal stripes with repetitive "Fentanyl" in grey font alternating with grey diagonal stripes with repetitive "100 µg/h" in beige font.

Each patch has a sticky back so that it can be stuck onto the skin. The patch is covered by two transparent oversized protective films which are both removed prior to application.

Fentanyl Zentiva is available in packs of 3, 4, 5, 8, 9, 10, 16, 19 or 20 transdermal patches. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited
12 New Fetter Lane
London EC4A 1JP
United Kingdom

Under license by Lavipharm

Manufacturer:
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For information in large print, tape, CD or Braille, telephone 0800 7318450.

