



Package leaflet: Information for the patient



Fentanyl 50 micrograms/ml Injection
fentanyl citrate

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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet

1. What Fentanyl 50 micrograms/ml Injection is and what it is used for
2. What you need to know before you are given Fentanyl 50 micrograms/ml Injection
3. How Fentanyl 50 micrograms/ml Injection is given
4. Possible side effects
5. How to store Fentanyl 50 micrograms/ml Injection
6. Contents of the pack and other information

1. What Fentanyl 50 micrograms/ml Injection is and what it is used for

This medicine has been prescribed for you and is used:

- in anaesthesia
- as a pain relief agent
- to induce calmness
- as a premedication to sedate and prepare a patient for general anaesthesia

This medicine contains fentanyl which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you.

Opioids can cause addiction and you may get withdrawal symptoms if you stop receiving it suddenly. Your prescriber should have explained how long you will be receiving it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you are given Fentanyl 50 micrograms/ml Injection

You should NOT be given Fentanyl 50 micrograms/ml Injection:

- if you are allergic to Fentanyl 50 micrograms/ml Injection, drugs similar to morphine or muscle relaxants, or any of the ingredients in this injection (listed in section 6).
- if you have any breathing problems or a lung disorder, such as asthma, chronic bronchitis or emphysema.
- if you are taking, or have taken, monoamine oxidase inhibitor (MAOI) drugs for depression, in the last 2 weeks.
- if you are in labour or before the cord is clamped during a Caesarean section. Fentanyl injection may affect the baby's breathing.

Warnings and precautions

Talk to your doctor or nurse before you receive Fentanyl 50 micrograms/ml Injection if you:

- have myasthenia gravis
- have reduced blood volume or low blood pressure
- have an under active thyroid gland
- have liver or kidney disease
- have problems with your lungs
- have a recent head injury
- are elderly or weak due to ill health
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Fentanyl 50 micrograms/ml Injection, it is important that you consult your doctor. Your prescriber should have explained how long you will be receiving 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 receiving 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 receiving 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.

Receiving higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Special monitoring

- Fentanyl 50 micrograms/ml Injection may make you breathe more slowly. Your breathing will be carefully monitored until it returns to normal.
- Your blood pressure and heart rate may also be monitored.

Other medicines and Fentanyl 50 micrograms/ml Injection

Concomitant use of fentanyl 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 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.

Tell your doctor or nurse if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription.

In particular, do not have this medicine and tell your doctor or nurse if you have taken:

- medicines for depression called 'monoamine oxidase inhibitors' (MAOIs). You should not have this medicine and should tell your doctor or nurse if you have taken these medicines in the past two weeks

This is especially important with the following medicines as they may interact with your Fentanyl 50 micrograms/ml Injection:

- medicines for depression called Selective Serotonin Reuptake Inhibitor (SSRIs) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine)

- medicines for putting you to sleep called "anaesthetic agents" and muscle relaxants
- clonidine
- pain relieving drugs (opioid analgesics) such as morphine or codeine
- some painkillers for nerve pain (gabapentin and pregabalin)
- medicines for anxiety or to help you sleep such as tranquillisers or sleeping pills
- medicines that affect your central nervous system (CNS depressants) such as medicine for mental disorder or alcohol
- medicines for treating a fungal infection (such as fluconazole or voriconazole)
- antiviral medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir, indinavir or saquinavir

The dose of etomidate and midazolam may need to be reduced if given together with fentanyl.

Pregnancy and breast-feeding

You should not be given Fentanyl 50 micrograms/ml Injection if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you receive Fentanyl 50 micrograms/ml Injection during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated. The doctor will then decide if the injection is suitable for you. Fentanyl 50 micrograms/ml Injection should not be used during childbirth as it can affect the baby's breathing.

You should not be given Fentanyl 50 micrograms/ml Injection while you are breastfeeding as fentanyl passes into breast milk and will affect your baby. Do not breast-feed or use breast milk that had been expressed for 24 hours after having Fentanyl 50 micrograms/ml Injection.

Driving and using machines

You should not drive or use machinery if you are affected by the administration of Fentanyl 50 micrograms/ml Injection.

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here:

<https://www.gov.uk/drug-driving-law>

The medicine can affect your ability to drive as it may make you feel sleepy or dizzy.

- Do not drive while receiving 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 received 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 receiving this medicine.

Fentanyl 50 micrograms/ml Injection contains sodium

This medicine contains:

- 7.1 mg (or 0.31 mmol) sodium (main component of cooking/table salt) per 2 ml ampoule, that is to say essentially 'sodium-free'.
- 35.4 mg (or 1.54 mmol) sodium (main component of cooking/table salt) per 10 ml ampoule. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.
- 177 mg (or 7.70 mmol) sodium (main component of cooking/table salt) per 50 ml vial. This is equivalent to 9% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Fentanyl 50 micrograms/ml Injection is given

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

Your prescriber should have discussed with you, how long the course of fentanyl will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop receiving the medicine.

If you are given more Fentanyl 50 micrograms/ml Injection than you should

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much or you begin to experience breathing difficulties, muscle stiffness, dizziness or symptoms of low blood pressure and a slower heartbeat, you must tell the person giving you the injection immediately. A brain disorder (known as toxic leukoencephalopathy) has also been observed with fentanyl overdose.

If you stop being given Fentanyl 50 micrograms/ml Injection

Do not suddenly stop receiving this medicine. If you want to stop receiving this medicine, discuss this with your prescriber 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. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop receiving this medicine.

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

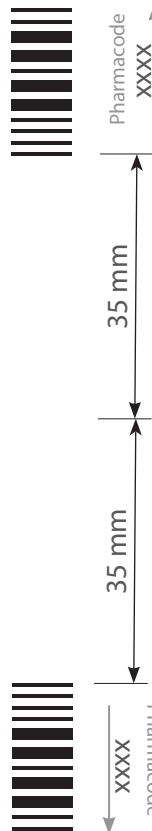
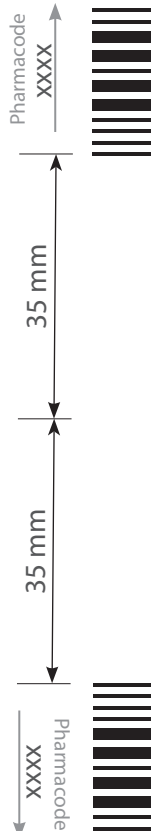
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects are serious and should you suffer any of the following please contact your doctor **immediately/** go to the nearest accident & emergency unit:

- Anaphylaxis which can include shortness of breath, difficulty breathing, skin rash, irregular skin patches and itching
- Bronchospasm - spasms in the throat
- Slow heartbeat

The following side effects have been reported:

Very common (affects more than 1 in 10 people)



- feeling sick (nausea), being sick (vomiting)
- muscle stiffness (which may involve your chest muscles)

Common (affects fewer than 1 in 10 people)

- agitation
- drowsiness
- dizziness
- problems with vision
- difficulty in breathing or wheezing
- choking caused by cramping (spasm) of the muscles in your throat
- stopping breathing for a short period of time. If necessary, your breathing will be helped by a machine (ventilator)
- low or high blood pressure
- irregular heartbeat (slow or fast)
- pain in your veins
- difficulty with body movements
- skin rash
- confusion after the operation

Uncommon (affects fewer than 1 in 100 people)

- changes in blood pressure
- breathing complications
- breathing faster than normal
- fall in body temperature below normal or chills
- headache
- swelling and clotting in a vein
- sweating
- hiccups
- cough
- difficulty in swallowing
- feeling of extreme happiness

Other side effects (frequency not known)

- serious allergic reaction which may cause difficulty in breathing or dizziness, and hives or nettle rash (urticaria)
- convulsions (fits or seizures)
- loss of consciousness
- muscle twitching
- stopping of the heart
- slow or shallow breathing
- itching of the skin
- spasm of the sphincter of Oddi (pain in stomach/abdomen)
- dependence and addiction (see section "How do I know if I am addicted?").
- Delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)

Drug Withdrawal

When you stop receiving Fentanyl 50 micrograms/ml Injection, 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 receiving Fentanyl 50 micrograms/ml Injection, it could be a sign that you have become addicted.

- You need to receive 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 receiving the medicine you feel unwell, and you feel better once receiving the medicine again.

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

Other side effects when Fentanyl 50 micrograms/ml Injection is used together with medicines called neuroleptics, which can be given before or during an operation:

- shivering and restlessness
- seeing things that aren't there (hallucinations)
- unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, a shuffling walk and stiffness of the arms and legs.

If you think this injection is causing you any problems, or you are at all worried, talk to your doctor, nurse or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor 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 - website: 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 50 micrograms/ml Injection

Keep this medicine out of the sight and reach of children.

Your injection will be stored at less than 25°C and protected from light.

Do not use this medicine after the expiry date which is stated on the label / carton after "EXP:". The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Fentanyl 50 micrograms/ml Injection contains

The active substance is fentanyl citrate. In Fentanyl 50 micrograms/ml Injection each 1 ml of solution contains the equivalent of 50 micrograms of fentanyl.

The other ingredients are sodium chloride, water for injections, and hydrochloric acid or sodium hydroxide.

What Fentanyl 50 micrograms/ml Injection looks like and contents of the pack

Fentanyl 50 micrograms/ml Injection is a clear, colourless and sterile solution for injection.

The following pack sizes are available for Fentanyl 50 micrograms/ml Injection:

- 2 ml clear glass ampoules: packs of 5 or 10
- 10 ml clear glass ampoules: packs of 5 or 10
- 50 ml clear glass vial, closed with a bromobutyl rubber stopper: packs of 1

Not all ampoule and pack sizes may be marketed.

The marketing authorisation number of this medicine is: PL 01502/0062

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For any information about this medicine, please contact the Marketing Authorisation Holder

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