

Package leaflet: Information for the user

Fentanyl 100 micrograms in 2ml Solution for Injection Fentanyl 500 micrograms in 10ml Solution for Injection fentanyl citrate

Read all of this leaflet carefully before you are given 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 of the side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet describes two strengths of the Injection. For simplicity they will both be referred to as Fentanyl injection.

What is in this leaflet:

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

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

Fentanyl injection is a type of medicine called an opioid analgesic. The word opioid means a substance similar to opium, for instance strong pain relievers such as morphine or codeine.

An analgesic is a medicine that can be used to relieve pain. In low doses, Fentanyl injection is used to provide pain relief during short surgical procedures and as a medicine given before administration of an anaesthetic. It may also be used in combination with antipsychotic drugs to provide pain relief. In higher doses, Fentanyl injection is used to provide pain relief in patients whose breathing needs to be assisted during surgery.

2. What you need to know before you are given Fentanyl Injection

You should not be given Fentanyl Injection :

- if you are allergic to fentanyl citrate or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to strong pain relievers such as morphine
- if you have any problems that affect your breathing such as asthma, chronic bronchitis or emphysema
- if you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs (eg. phenelzine or isocarboxazid) are medicines used to treat depression
- if you have just had an operation in the gall bladder area
- if you have raised pressure in the brain or coma from a head injury or brain disease
- if you are under the influence of excess alcohol.

Speak to your doctor if one of these applies to you *before* you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before you are given Fentanyl Injection/Infusion if:

- you have an underactive thyroid gland (which may cause tiredness, intolerance to cold, constipation, and puffiness of the face)
- you have any problems with your lungs or breathing
- you have a problem with your liver or kidneys
- you have a low blood pressure or slow heart rate
- you are taking medications such as citalopram, which are used to treat depression (low mood)

- you have a problem with blood circulation in your brain.
- you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Fentanyl may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.
- 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 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 Injection, it is important that you consult your doctor.

Speak to your doctor if one of these applies to you *before* you are given this medicine. In certain cases, your doctor may need to monitor your heart with an electrocardiogram (ECG) before starting or during treatment with Fentanyl injection. Also your breathing will be carefully monitored and your doctor will have special equipment and drugs available to reverse any lowering of your breathing rate.

If your treatment is stopped withdrawal symptoms may occur. Please tell your doctor or nurse if you think this is happening to you (see also section 4. Possible side effects).

Other medicines and Fentanyl Injection

Tell your doctor if you are taking, have recently taken or might take any other medicines.

A large number of drugs can interact with Fentanyl injection which can significantly alter their effects. These include:

- depression and anxiety
- schizophrenia or other serious mental illness
- allergies
- pain, especially strong morphine-based painkillers and cough suppressants
- some painkillers for nerve pain (gabapentin and pregabalin)
- sleeping tablets
- muscle relaxants.

Other medicines which may interact with Fentanyl are:

- Cimetidine (for heartburn or stomach ulcer)
- Betablockers such as atenolol and bisoprolol used to treat heart problems and high blood pressure
- Diltiazem (used to treat high blood pressure and chest pain)
- Medicines used during surgery to relax muscles such as suxamethonium and vecuronium
- Halothane, a gas used in general anaesthesia
- Medicines for putting you to sleep, also known as ‘anaesthetic agents’ (such as etomidate)
- Medicines for anxiety or to help you sleep (e.g. Midazolam)
- Medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir
- Medicines for fungal infection (such as Itraconazole, fluconazole or voriconazole)
- 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.

You should also tell your doctor if you take alcohol regularly. If you are already taking one of these medicines, speak to your doctor before you are given Fentanyl Injection.

Fentanyl Injection with food and drink and alcohol

You must tell your doctor if you drank a lot of alcohol within 24 hours before you are given Fentanyl injection, or are planning to drink a lot of alcohol after you have been given this injection.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, inform your doctor or nurse before this medicine is given to you.

There is no evidence of harmful effects in pregnancy. However, as with all drugs Fentanyl injection should only be given in pregnancy if absolutely necessary. You should not be given Fentanyl injection if you are in labour or if you are breast-feeding.

Driving and using machines

Fentanyl injection can cause drowsiness and clouding of consciousness which could interfere with your ability to drive or to use machines. Do not drive or operate machinery after receiving this medicine. When your Fentanyl injection treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

Information on Sodium content

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How Fentanyl Injection is given to you

Fentanyl injection is administered by injection into a vein and will be administered by your doctor or nurse.

Your doctor will choose the most suitable dose for your needs. In adults the dose may range from 100 to 800 micrograms depending on the circumstances.

In children the dose is calculated according to the child's weight. Elderly patients may require reduced doses.

If you think you have been given more Fentanyl Injection than you should have

This is unlikely as your injection will be administered by a doctor or nurse. If you think you have been given too much or you begin to experience breathing difficulties (symptoms of respiratory depression) or loss of coordination and/ or vision, difficulty walking, facial drooping, personality changes, trouble speaking, weak muscles (symptoms of toxic leukoencephalopathy, which is a brain disorder), you must tell your doctor or nurse immediately. If you are concerned about the dose, discuss this with your doctor.

If you think you have missed a dose of Fentanyl Injection

If you think that you have missed a dose, tell your doctor or nurse immediately. If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

All medicines can cause allergic reactions although serious allergic reactions are rare.

Any of the following side effects should be reported to a doctor immediately:

Not known (frequency cannot be estimated from available data)

- any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Other side effects:

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- changes in blood pressure
- breathing complications
- breathing faster than normal
- fall in body temperature below normal or chills
- headache
- agitation after the operation
- swelling or clotting in a vein
- feeling of extreme happiness
- hiccups
- difficulty in swallowing.

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

- hives or nettle rash (urticaria)convulsions (fits or seizures)
- loss of consciousness
- semi-consciousness or coma
- muscle twitching
- stopping of the heart
- slow or shallow breathing
- itching of the skin
- unusual increase in sense of smell, taste, touch, feel (e.g. feel of pain) or hearing
- cough
- constipation
- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- symptoms of withdrawal syndrome (may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating).

Other side effects when Fentanyl 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, shuffling walk and stiffness of the arms and legs.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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 HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fentanyl Injection

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

Do not use this medicine after the expiry date which is stated on the ampoule and carton after 'EXP'. The expiry date refers to the last day of that month.

Keep the ampoule in the outer carton in order to protect from light. Do not store above 25°C.

If only part of the contents of an ampoule is used, the remaining solution should be discarded.

If the solution appears strongly coloured it should not be used.

For single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fentanyl Injection contains

-The active substance is Fentanyl present as fentanyl citrate.

Fentanyl 100micrograms in 2ml: Each 2ml ampoule contains 100 micrograms of fentanyl as fentanyl citrate.

Fentanyl 500micrograms in 10ml: Each 10ml ampoule contains 500 micrograms of fentanyl as fentanyl citrate.

-The other ingredients are sodium chloride, sodium hydroxide and water for injections.

What Fentanyl injection looks like and contents of pack

Fentanyl 100 micrograms in 2ml solution for injection is a clear, colourless, sterile solution for injection. Each 2ml glass ampoule contains 100 micrograms of active ingredient fentanyl as fentanyl citrate. Each pack contains 10 ampoules.

Fentanyl 500 micrograms in 10ml solution for injection is a clear, colourless, sterile solution for injection. Each 10ml glass ampoule contains 500 micrograms of active ingredient fentanyl as fentanyl citrate. Each pack contains 10 ampoules.

Marketing Authorisation Holder

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