

**Package leaflet: Information for the user**  
**Fentanyl 100 micrograms in 2ml Solution for**  
**Injection**  
**Fentanyl 500 micrograms in 10ml Solution for**  
**Injection**  
Fentanyl

**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 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 this medicine if:**

- you are allergic to Fentanyl citrate or any of the other ingredients of this medicine (listed in section 6).
- you are allergic to strong pain relievers such as morphine
- you have any problems that affect your breathing such as asthma, chronic bronchitis or emphysema
- 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
- you have just had an operation in the gall bladder area
- you have raised pressure in the brain or coma from a head injury or brain disease
- 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 are dependent on drugs including alcohol and opioids
- 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.

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.

### **Tolerance and dependence:**

Fentanyl Injection/Infusion can become less effective with repeated use. This is called tolerance and it means that the dose may have to be increased for Fentanyl Injection/Infusion to work as well as it did previously.

If Fentanyl Injection/Infusion is used too often, it becomes habit-forming. This is called dependence and if Fentanyl Injection/Infusion treatment is suddenly stopped, you may experience withdrawal symptoms.

### **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
- 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)

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.

### **Taking 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.

### **Important information about some of the ingredients of Fentanyl Injection**

This medicine contains 3.542mg sodium per ml which should be taken into consideration by patients on a sodium controlled diet and receiving more than 6.5ml.

### **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 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.

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

- serious allergic reaction which may cause difficulty in breathing or dizziness
- 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.

**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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie) E-mail: [medsafety@hpra.ie](mailto:medsafety@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**

Mercury Pharmaceuticals (Ireland) Ltd, 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

### **Manufacturer**

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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