

## Package leaflet: Information for the user

### Fentanyl 50micrograms/ml Solution for Injection/Infusion

fentanyl citrate

**This medicine contains Fentanyl which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop being given it suddenly.**

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

The name of your medicine is Fentanyl 50 micrograms/ml Solution for Injection/Infusion. It will be referred to as Fentanyl Injection/Infusion for ease hereafter.

#### **What is in this leaflet:**

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

#### **1. What Fentanyl Injection/Infusion is and what it is used for**

This medicine has been provided to you for pain relief during short surgical procedures (in low doses) and as a medicine given before administration of an anaesthetic. In higher doses, Fentanyl Injection/Infusion is used to provide pain relief in patients whose breathing needs to be assisted during surgery. It contains the Fentanyl which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been provided to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop being given it suddenly. Your prescriber should have explained how long you will be given this medicine for and when it is appropriate to stop, how it is done safely.

#### **2. What you need to know before you are given Fentanyl Injection/Infusion**

##### **You should not be given Fentanyl Injection/Infusion**

- 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 other strong pain relievers, such as morphine
- if you have any problems that affect your breathing including obstructive airways disease like chronic bronchitis or emphysema or respiratory depression (reduced respiratory rate)
- after surgery on the biliary tract.

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:

- your blood pressure is abnormally low, or you have an underactive thyroid gland (which may cause tiredness, intolerance to cold, constipation and puffiness of the face)
- you have a condition that makes you have fits, e.g. epilepsy
- you have a problem with your liver, lungs or kidneys

- you have any kind of heart disease (e.g. abnormalities of heart rate or rhythm, heart blocks, inadequate blood supply to heart)
- you suffer from myasthenia gravis, where your body's immune system fights its own body
- you are dehydrated or have had any recent bleeding
- 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 have a problem with alcohol or have taken alcohol within the previous 24 hours
- low blood volume
- you are elderly or weak due to ill health
- administered during labour, Fentanyl Injection/Infusion may affect the baby's breathing.
- 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.

Talk to your prescriber before you are given this medicine if:

- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs. 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/Infusion, it is important that you consult your doctor.

Being given this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be given this medicine for and when it is appropriate to stop, how it is done 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 are stopped being given 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 your dose will be gradually reduced before stopping the medicine. It is important that you should not stop being given the medicine suddenly as you will be more likely to experience withdrawal symptoms.

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

In certain cases, your doctor may need to monitor your heart with an electrocardiogram (ECG) before starting or during treatment with Fentanyl Injection/Infusion. Speak to your doctor if one of these applies to you before you are given this medicine.

#### **Other medicines and Fentanyl Injection/Infusion:**

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/Infusion which can significantly alter their effects. These drugs include:

- medicines for anxiety or to help you sleep (e.g. benzodiazepines such as diazepam or midazolam).
- medicines used to treat HIV infection such as ritonavir.
- phenytoin or phenobarbital (to treat epilepsy).
- other strong medicines for pain called ‘opioid analgesics’ such as morphine or codeine.
- some painkillers for nerve pain (gabapentin and pregabalin).
- medicines for treating a fungal infection such as itraconazole, fluconazole or voriconazole.
- medicines for stomach ulcer e.g. cimetidine.
- medicines used as antipsychotics and prevent vomiting e.g. droperidol.
- medicines used to lower blood pressure (e.g. beta-blockers such as metoprolol).
- CYP3A4 inhibitors (e.g. diltiazem used to treat high blood pressure and chest pain).
- medicines for treatment of low mood (depression) e.g. monoamine-oxidase Inhibitors (MAOI).
- medicines used in surgery such as halothane, etomidate (anaesthetic agents) and suxamethonium, vecuronium (muscle relaxants)’.- medicines for low mood (depression) (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine).
- 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.

If you are already taking one of these medicines, speak to your doctor before you receive Fentanyl Injection/Infusion.

**Fentanyl Injection/Infusion with food, drink and alcohol:**

You must tell your doctor if you drank a lot of alcohol within 24 hours before you are given Fentanyl Injection/Infusion, 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.

Pregnancy

You should not be given Fentanyl Injection/Infusion 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 Fentanyl Injection/Infusion is given during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

You should not be given Fentanyl Injection/Infusion while you are breastfeeding as Fentanyl passes into breast milk and will affect your baby.

**Driving and using machines:**

Fentanyl Injection/Infusion 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/Infusion treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

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

- Do not drive while you are given 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 been given 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 nurse if you are not sure whether it is safe for you to drive after receiving this medicine.

**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/Infusion is given to you**

Your prescriber should have discussed with you, how long the course of Fentanyl Injection/Infusion will last. They will arrange a plan for stopping treatment. This will outline how gradually the dose is reduced and stop being given.

Fentanyl Injection/Infusion may be administered by injection into a muscle or by injection or infusion into the vein.

The recommended dose is:

Your doctor will choose the most suitable dose for your particular condition. Doses greater than 200 micrograms are only for use in anaesthesia, as higher doses may cause difficulty in breathing.

**If you think you have been given more Fentanyl Injection/Infusion 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/Infusion.**

If you think that you have missed a dose, tell your doctor or nurse immediately.

**If you stop being given Fentanyl Injection/Infusion**

You should not suddenly stop being given this medicine. If you want to stop being given this medicine, discuss this with your prescriber first. They will tell you how it is done, 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 are suddenly stopped being given this medicine.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side-effects, although not everyone 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):**

- involuntary, repetitive body movements
- drowsiness
- dizziness
- problems with vision
- rapid or slow heartbeats
- irregular heartbeats
- 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 (apnoea)
- skin rash
- confusion after the operation.

##### **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
- swelling and clotting in a vein
- hiccups
- mood elevation
- agitation after operation
- difficulty in swallowing.

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

- convulsions (fits or seizures)
- loss of consciousness
- muscle twitching
- stopping of the heart (cardiac arrest)
- 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)
- dependence and addiction (see section “How do I know if I am addicted?”)

If you received Fentanyl Injection/Infusion with a tranquiliser (such as droperidol) and you notice any of the following effects, tell your doctor:

- shivering and restlessness
- seeing or hearing 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.

Drug Withdrawal: When you are stopped being given Fentanyl Injection/Infusion, you may experience drug withdrawal symptoms, which include nausea, vomiting, chills, 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 being given fentanyl, it could be a sign that you have become addicted.

- You are given the medicine for longer than advised by your prescriber
- You feel you need to be given more than the recommended dose
- You are being given the medicine for reasons other than prescribed
- When you are stopped being given the medicine, you feel unwell, and you feel better once given the medicine again.

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

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

### **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, website: [www.mhra.gov.uk/yellowcard](http://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 Injection/Infusion**

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 label after “Exp”. The expiry date refers to the last day of that month.

Fentanyl Injection/Infusion should be protected from light and stored below 25°C.

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

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.

### **6. Contents of the pack and other information**

#### **What Fentanyl Injection/Infusion contains**

The active substance is fentanyl citrate.

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

**What Fentanyl Injection/Infusion looks like and contents of pack**

Fentanyl Injection/Infusion is a clear, colourless, sterile solution. Each 1ml of solution contains 50mcg of fentanyl.

The solution is presented in clear glass ampoules (bottles), containing either 2ml or 10ml. The ampoules are then packed in cardboard cartons with 10 ampoules per box. Not all pack sizes may be marketed.

**Marketing authorisation holder:**

Mercury Pharmaceuticals Ltd  
Dashwood House,  
69 Old Broad Street,  
London, EC2M 1QS,  
United Kingdom.

**Manufacturer:**

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

This leaflet was last revised in March 2024.