Fentanyl Injection can be used in the following situations:

- To relieve severe pain.
- As a premedication for anaesthesia or surgery.
- As an adjuvant sedative in anaesthesia.
- To administer during resuscitation or in the intensive care unit.
- As a premedication before certain diagnostic tests.

It is important to read all of this leaflet carefully before you are given Fentanyl 50 micrograms/ml, Solution for Injection.

You should not be given Fentanyl Injection if you:

- Are allergic (hypersensitive) to fentanyl or any of the other ingredients (listed in section 6).
- Are suffering from severe undiagnosed headaches or have had a head injury.
- Are suffering from liver or kidney disease.
- Are receiving opioid therapy or have a history of opioid abuse.
- Have an under active thyroid gland.
- Are pregnant, planning to become pregnant or are breast-feeding.
- Are suffering from a muscle disorder known as myasthenia gravis.
- Have taken it according to the instructions given by the prescriber or in the information provided with the medicine.
- Have any of the above apply to you or your child, please consult your doctor.

Special Monitoring:

- Repeated use of fentanyl may make you feel drowsy or faint. These include CNS depressants (drugs that act on the brain and make you feel drowsy or faint). These include sleeping pills, antihistamines (medicines used to treat certain mental disorders, other painkillers or a general anaesthetic such as etomidate). Using Fentanyl Injection with food, drink and alcohol:

- You should not drink alcohol during your treatment with Fentanyl Injection.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.
- Fentanyl Injection should not be used during childbirth as it can affect the baby’s breathing.
- Fentanyl is excreted into breast milk. Do not breastfeed or use breast milk that has been expressed for 24 hours after having Fentanyl Injection.

Driving and using machines:

- Do not drive or use any tools or machines for at least 24 hours after having Fentanyl Injection. You may be less alert than usual. This medicine can affect your ability to drive as it may make you sleepy or dizzy.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine.
- If you are taking any of the above medicines, please talk to your doctor or nurse for advice before taking this medicine.

Possible side effects:

- Common side effects include:
  - Nausea
  - Vomiting
  - Constipation
  - Dry mouth
  - Headache
  - Dizziness
  - Tiredness
  - Inability to sleep
  - Rapid heart rate
  - Raised blood pressure
  - Sore throat
  - Cough
  - Difficulty breathing
  - Abnormal sensitivity to touch
  - Skin rash
  - Muscle cramps
  - Stiffness of the body

- Less common side effects include:
  - Confusion
  - Difficulty swallowing
  - Difficulty speaking
  - Changes in bowel movement
  - Blood in the urine
  - Changes in color vision
  - Decrease in sweating
  - Changes in taste
  - Sudden weight gain
  - Vision loss

- Rare side effects include:
  - Seizures
  - Slurred speech
  - Inability to move
  - Changes in behaviour
  - Changes in mood
  - Changes in personality
  - Changes in appetite
  - Changes in memory
  - Changes in sleep patterns
  - Changes in sexual function
  - Changes in eye or skin pigmentation
  - Changes in growth

- Severe side effects include:
  - Shock
  - Difficulty breathing
  - Changes in heart rate or blood pressure
  - Changes in breathing pattern
  - Changes in level of consciousness
  - Changes in blood tests

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

Like all medicines, Fentanyl injection can cause side effects, although not everybody gets them. If any of the following symptoms occur tell your doctor or nurse immediately. These are symptoms of a serious allergic reaction:

- sudden wheezing and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itching, fever
- collapse

Very common side effects (affect more than 1 in 10 people) include:

- muscle stiffness
- feeling sick (nausea), or being sick (vomiting)

Common side effects (affect less than 1 in 10 people) include:

- feeling agitated
- jerky or uncoordinated movements
- dizziness
- blurred vision, blind spots or haloes around lights (visual disturbances)
- a slow or irregular heartbeat
- unusually low or high blood pressure
- pain along your veins
- choking caused by cramping (spasm) of the muscles of your throat
- wheezing or difficulty breathing
- stopping breathing for a short period of time.

If necessary, your breathing will be helped by a machine (ventilator).
- an itchy rash or redness of the skin
- confusion

Uncommon side effects (affect less than 1 in 100 people) include:

- a feeling of extreme happiness (euphoria)
- headache
- swelling and cloting along a vein
- changes in blood pressure
- breathing faster than usual
- hiccups
- decrease in body temperature or chills
- breathing complications

Other side effects (frequency not known) include:

- a serious allergic reaction (see symptoms above)
- convulsions (fits or seizures)
- loss of consciousness
- muscle twitching
- stopping of the heart (cardiac arrest)
- slow or shallow breathing

Other side effects can occur when Fentanyl injection is used with a type of medicine called neuroleptics. These include:

- chills or shivering
- restlessness
- seeing or hearing things that aren't real (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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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, Solution for 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 carton and ampoule label after “EXP”.

The expiry date refers to the last day of that month.

Do not use this medicine if you notice any discolouration or there are particles in it. If only part of the solution is used, the remainder should be discarded.

Do not store above 25°C and keep container in the outer carton to protect from light.

6. Content of the pack and other information

What Fentanyl 50 micrograms/ml, Solution for Injection contains

Active ingredient: fentanyl citrate 78.5 micrograms/ml equivalent to 50 micrograms fentanyl.

Other ingredients: sodium chloride, sodium hydroxide (for pH-adjustment), water for injections

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

The clear colourless solution is presented in 2 or 10 ml clear glass ampoules in packs of 10 ampoules.

Not all pack sizes may be marketed.