

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fentanyl 50 micrograms/ml Solution for Injection

fentanyl

Read all of this leaflet carefully before you are given Fentanyl 50 micrograms/ml, Solution for Injection.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or nurse.
- 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.

What is in this leaflet:

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

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

Fentanyl belongs to a group of medicines called opioid analgesics, often used in anaesthesia or as a painkiller.

Fentanyl Injection can be used in the following situations:

- In low doses it is used to provide pain relief during short surgical procedures
- Where breathing is assisted, it is used in higher doses as an anaesthetic and analgesic
- To provide pain relief
- For the treatment of severe pain.

2. What you need to know 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 other opioid medicines or any of the other ingredients (listed in section 6)
- suffer from asthma, shallow breathing or other breathing difficulties

- are taking or have recently (within the last two weeks) taken any drugs used to treat depression known as Monoamine Oxidase Inhibitors (MAOI's) (see 'Taking other medicines')

Warning and precautions

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

- are pregnant, planning to become pregnant or are breast-feeding
- have an under active thyroid gland
- are suffering from lung disease
- suffer from a muscle disorder known as myasthenia gravis
- are suffering from liver or kidney disease
- are receiving opioid therapy or have a history of opioid abuse
- suffer from alcoholism
- are suffering from severe undiagnosed headaches or if you have recently suffered a head injury
- have been told you are suffering from low blood volume
- have pain in right upper side of your abdomen (bile duct).
- have been administered during labour, fentanyl injection may affect the baby's breathing.

If any of the above apply to you or your child, please consult your doctor.

Special Monitoring

- Repeated use of fentanyl can result in tolerance and addiction.
- Your doctor will take special care when giving you this medicine if you are elderly or weak due to ill health or if you are in labour.
- Fentanyl Injection may make you breathe more slowly than usual or can cause shortness of breath. You will only be given this medicine where you can be carefully monitored until your breathing returns to normal.
- Your blood pressure and heart rate may also be monitored.

Tell your doctor if you have ever abused or been dependent on opioids, alcohol, prescription medicines, or illegal drugs.

Repeated use of the product may result in the drug being less effective (you become accustomed to it) or becoming dependent on it.

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 50 micrograms/ml, Solution for 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.

Fentanyl Injection **must not** be used with drugs used to treat severe depression, such as phenelzine or moclobemide, or if you have stopped taking them within the last 2 weeks. These drugs are known as Monoamine Oxidase Inhibitors (MAOI's).

Please tell your doctor or nurse if you:

- are taking Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) for depression (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine).
- are taking any major tranquilizer (antipsychotic) drug.

Medicines which may interact with Fentanyl Injection 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 allergies) that make you drowsy, medicines used to treat certain mental disorders, other pain killers or a general anaesthetic such as etomidate.
- ritonavir, (a medication used to treat or prevent infection by viruses such as HIV) and other protease inhibitors such as indinavir and saquinavir.
- droperidol (a drug used to treat anxiety and sickness)
- muscle relaxants
- medicines used to treat fungal infections such as fluconazole or voriconazole
- midazolam (a medicine used to make you feel relaxed and sleepy before an operation)

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

If you are taking any of the above medicines, please tell your doctor as Fentanyl Injection may increase the effects of these drugs or prevent them from working properly.

Using Fentanyl Injection with food, drink and alcohol:

You should not drink alcohol during your treatment with Fentanyl Injection.

Pregnancy and breast-feeding:

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.

- Do not drive while taking 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 taken 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 taking this medicine.

Fentanyl Injection contains sodium

If you need to control your salt intake (controlled sodium diet) be aware that:

- Fentanyl Injection contains 3.5 mg sodium in each ml of solution. This is equivalent to 0.18% of the recommended maximum daily dietary intake of sodium for an adult.
- The contents of the ampoule may be diluted in a salt solution before being given to you. This salt solution also contains sodium

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3. How Fentanyl 50 micrograms/ml, Solution for Injection is given

This medicine is an injection and will be given to you by your doctor. Your doctor will determine the dose you need based on your age, body weight, general health and whether you are taking any other medicines.

Fentanyl Injection is given into a vein either by injection or infusion (drip). Under some circumstances your doctor may prescribe a dose higher than those stated here.

Adults and children aged 12 to 17 years old: During surgery if you are able to breathe on your own

The usual initial dose is between 50 and 200 micrograms, followed by a further dose of 50 micrograms if needed.

During surgery if your breathing is assisted

The usual initial dose is between 300 and 3500 micrograms, followed by a further dose of 100-200 micrograms if needed.

By Infusion (drip)

The usual initial dose is 1 microgram per kilogram every minute for the first 10 minutes, followed by a further dose of 0.1 microgram per kilogram every minute for the duration of your operation. The drip will normally be stopped 40 minutes before the end of your operation.

Elderly:

If you are elderly you will be given a reduced dose.

Use in children aged 2 to 11 years old:

During surgery if your child is able to breathe on their own

The usual initial dose is between 1 and 3 micrograms per kilogram of body weight, followed by a further dose of 1-1.25 micrograms per kilogram of body weight if needed.

During surgery if your child's breathing is assisted

The usual initial dose is between 1 and 3 micrograms per kilogram of body weight, followed by a further dose of between 1-1.25 micrograms per kilogram of body weight if needed.

If you are given more Fentanyl 50 micrograms/ml, Solution for Injection than you should be:

As Fentanyl Injection will be given to you in hospital by a doctor it is unlikely you will be given too much, however tell your doctor or nurse if you think you have been given too much of this medicine or you begin to experience breathing difficulties, dizziness or symptoms of low blood pressure or muscle stiffness.

4. 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 wheeziness and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itchiness, 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)

- feeling agitated
- jerky or uncoordinated movements
- drowsiness
- 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 clotting 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
- itching of the skin
- symptoms of withdrawal syndrome (may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating)

- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)

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 discoloration 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 maybe marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Martindale Pharmaceuticals Ltd.,
Bampton Road, Harold Hill,
Romford, Essex. RM3 8UG UK

Manufacturer:
Macarthys Laboratories Limited
Bampton Road
Romford
Essex, RM3 8UG

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Fentanyl Ethypharm
Finland:	Fentanyl Ethypharm 50 mikrog / ml injektioneste, liuos
France:	Fentanyl Ethypharm 50 mcg/ml solution for injection
Germany:	Fentanyl Ethypharm 50 Mikrogramm / ml Injektionslösung
Italy:	Fentanil Ethypharm
Norway:	Fentanyl Ethypharm
Spain:	Fentanilo Ethypharm 50 microgramos/ml solución inyectable
Sweden:	Fentanyl Ethypharm 50 mcg/ml injektionsvätska, lösning
United Kingdom:	Fentanyl 50 micrograms/ml Solution for Injection

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 **MARTINDALE PHARMA**
Bampton Road, Harold Hill, Romford, RM3 8UG, UK

D04983 0.0.0.0

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MARTINDALE PHARMA

DEVELOPMENT ARTWORK

Component Code: D04983

Prod: Fentanyl 50mcg/ml PIL UK

Paper Size: 260 x 340mm

Version Control	Date	By
Version A :	24/05/19	NF
Version B:	29/05/19	SS
Version C:		
Version D:		
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		

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