

Fentanyl MediS® 0.5 mg/10 ml - Fentanyl MediS® 0.1 mg/2 ml
solution for injection/infusion
Fentanyl citrate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 pharmacist

In this leaflet:

1. What Fentanyl MediS is and what it is used for
2. What you need to know before you are given Fentanyl MediS
3. How Fentanyl MediS is given to you
4. Possible side effects
5. How to store Fentanyl MediS
6. Further information

1. What Fentanyl MediS is and what it is used for?

Fentanyl MediS 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 MediS is used to provide pain relief during short surgical procedures and as a medicine given before administration of an anaesthetic. In higher doses, Fentanyl MediS 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 MediS:

You should not be given this medicine if:

- you are allergic to Fentanyl or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to other strong pain relievers, such as morphine
- 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 MediS 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 MediS may affect the baby's breathing.

Tolerance and dependence:

Fentanyl can become less effective with repeated use. This is called tolerance and it means that the dose may have to be increased for Fentanyl to work as well as it did previously. If Fentanyl is used too often, it becomes habit-forming. This is called dependence and if Fentanyl treatment is suddenly stopped, you may experience withdrawal symptoms. In certain cases, your doctor may need to monitor your heart with an electrocardiogram (ECG) before starting or during treatment with Fentanyl. Speak to your doctor if one of these applies to you before you are given this medicine.

Other medicines and Fentanyl MediS:

Tell your doctor if you are taking, have recently taken or might take any other medicines. Fentanyl MediS can interact with Fentanyl 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.
- 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).

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

Fentanyl MediS 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 MediS, or are planning to drink a lot of alcohol after you have been given this injection.

Pregnancy, breast-feeding and fertility:

Pregnancy, breast-feeding and fertility: 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 breast-feeding as Fentanyl passes into breast milk and will affect your baby.

Driving and using machines

Fentanyl MediS 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 MediS 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 sleep 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 nurse if you are not sure whether it is safe for you to drive after receiving this medicine.

List of excipient with known effect: sodium.

3. How Fentanyl MediS is given to you

Fentanyl MediS may be administered by epidural route or by injection or infusion into the vein.

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 MediS 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 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
- 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.

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.

If you received Fentanyl MediS with a tranquilliser (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.

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.

5. How to store Fentanyl MediS:

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 MediS should be protected from light and stored below 30°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.

Shelf life:

- Fentanyl MediS 0.5 mg/10 ml: 24 months

- Fentanyl MediS 0.1 mg/2 ml: 36 months

6. Further information

A-What Fentanyl MediS contains:

The active substance is fentanyl citrate.

	Fentanyl MediS 0.1mg/2ml	Fentanyl MediS 0.5mg/10ml
Active substance:		
Fentanyl citrate	157 µg (0.1 mg as base)	785 µg (0.5 mg as base)
Excipients:		
Sodium chloride	17.8 mg	89.00 mg
water for injection	2 ml	10 ml

b-What Fentanyl MediS looks like and contents of pack:

Fentanyl MediS 0.1 mg/2 ml: injectable solution, box of 10 ampoules of 2 ml

Fentanyl MediS 0.5 mg/10 ml: injectable solution, box of 10 ampoules of 10 ml

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Salehiya Trading Company
(medical equipment & pharmaceuticals)
P.O. Box 991, Riyadh 11421- Kingdom of Saudi Arabia
Tel: 00 966 1 46 46 955
Fax: 00 966 1 46 34 362

c- This leaflet was last approved in: 09/2021; version number: V00

d- To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- o Fax: +966 11-205-7662
- o Call NPC at +966 11-2038222. Exts: 2317-2356-2353-2354-2334-2340.
- o Toll free phone: 8002490000
- o E-mail: npc.drug@sfd.gov.sa
- o Website: www.sfd.gov.sa/npc

• Other GCC states:

- Please contact the relevant competent authority.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers, Union of Arab Pharmacists

