

FENTANYL MédiS® 0,1 mg/2 ml - FENTANYL MédiS® 0.5 mg/10 ml

Injectable solution in ampoule (IV and epidural route)

DCI : Fentanyl citrate

Please read carefully the integrality of this notice before taking this drug.

- Keep this notice; you may need to read it again.
- If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
- This drug was prescribed for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
- If one of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

In this notice:

1. What FENTANYL MédiS is and what is used for?
2. Before you take FENTANYL MédiS:
3. How to use FENTANYL MédiS?
4. Possible side effects:
5. How to store FENTANYL MédiS?
6. Further Information:

1. What FENTANYL MédiS is and what is used for?

This drug is a central analgesic (against pain).
This drug is reserved to the long, mean and short duration anesthesia.
It can also be used:

- Post-operative pains exclusively in patients under intensive medical monitoring.
- By epidural route, combined to a local anesthetic.

2. Before you take FENTANYL MédiS:

Do not take FENTANYL MédiS in the following cases:

- Known allergy to fentanyl ;
- During pregnancy ;
- Respiratory difficulties requiring assistance equipments ;
- Combination to certain analgesics: nabalphine, buprenorphine, pentazocine.

In case of doubt, it is necessary to ask your doctor's advice.
In case of use of this drug, alcohol drinks or drugs containing alcohol consumption is not recommended.

Take special care with FENTANYL MédiS

- In cardiac surgery, fentanyl is to be used with caution in patients treated by certain nonselective MAOI antidepressants (nialamide, iproniazide).
- This drug contains sodium; this is to be taken into the account in persons under strict poor in salt diet.

This drug should be used with caution in case of:

- Non controlled cardiac insufficiency;
- Cerebral circulation disorders ;
- Chronic respiratory disease;
- Renal or hepatic insufficiency;
- Non controlled hypothyroidism (thyroid hormones insufficiency).

A tight medical monitoring will be performed in during the use of this drug. Anyway, your doctor will take the appropriate dispositions.

A specialized post-operative monitoring is always planned in all cases.

Taking FENTANYL MédiS with other medicines

This drug must not be administered concomitantly with certain morphine containing analgesics: nabalphine, buprenorphine, and pentazocine.
Alcohol drinks or drugs containing alcohol consumption are formally not recommended.

If you take or you have recently taken other drugs, even those obtained without medical prescription, inform your doctor or your pharmacist.

Taking FENTANYL MédiS with foods and drinks

Alcohol drinks consumption is formally not recommended.

Pregnancy and breastfeeding

In certain cases, this drug can be used during pregnancy.
Some precautions should be taken during childbirth, if the use of fentanyl proved to be necessary.

After the administration of fentanyl, it is advised to wait 4 hours before breastfeeding.
Ask your doctor or your pharmacist advice before taking any drug.

Sportmen and sportswomen

This drug can induce a positive reaction in test practiced for the anti-doping controls.

Driving and use of machines

After the administration of fentanyl, driving or using machines can be harmful during a certain moment. The patients must not drive and must be escorted home.

Important information concerning some components of FENTANYL MédiS

List of excipients with known effect:

Sodium.

3. How to use FENTANYL MédiS?

This product must only be administered by doctors specialized in anesthesiology or in emergency medicine and who are familiarized with anesthetics use, or under their control. They must dispose of the required anesthesiology equipments.

The usual dose is:

The dosage is strictly determined by the doctor.

Mode of administration:

Intravenous or epidural route.

Frequency of administration

The frequency and the moment of administration will be determined by the doctor.

Treatment duration

The treatment duration will be determined by the doctor.

The IV administration of sodium nafcilline rapidly followed by the administration of a combination of fentanyl and droperidol provokes the formation of a white precipitate. Due to the potential incompatibility which is susceptible to provoke precipitates formation, the mixes are to be avoided or to be validated and prepared by qualified hospital personnel in pharmacy.

If you used more FENTANYL MédiS than you should

In case of overdose, the doctor will take the appropriate dispositions

If you forgot to use FENTANYL MédiS

Not applicable.

If you discontinue FENTANYL MédiS

Not applicable.

4. Possible side effects

Like all the other drugs, FENTANYL MédiS can provoke undesirable effects. However, all the patients will not experience these effects.

- Respiratory difficulties, or even a respiratory failure, heart rate or blood pressure reduction, muscle rigidity, muscles twitches, nausea, vomiting, dizziness.

Some other less common undesirable effects were reported:

- Allergic reactions: Respiratory difficulties, itching, urticaria, face and neck edema, blood pressure failure with malaise.
- Post-operative respiratory depression.

If you note undesirable effects which are not mentioned in this notice, please inform your doctor or your pharmacist.

5. How to store Fentanyl MédiS?

To store at temperature below 30°C, away from light.

6. Further Information

Delivery conditions:

TABLE B - only under medical prescription - NARCOTIC

What are the components of FENTANYL MédiS?

	FENTANYL MédiS 0.1 mg/2 ml	FENTANYL MédiS 0.5 mg/10 ml
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 injectable préparations	s.q.f. 2 ml	s.q.f 10 ml

What is FENTANYL MédiS and external packaging content?

Fentanyl MédiS 0.1 mg / 2 ml - Fentanyl: injectable solution in ampoules of 02 ml packed in boxes of 10 ampoules of 2 ml - M.A.N°: 923 331 1H

Fentanyl MédiS 0.5 mg / 10 ml - Fentanyl: injectable solution in ampoules of 10 ml packed in boxes of 10 ampoules of 10 ml - M.A.N°: 923 331 1H

Marketing authorization holder and manufacturer :

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This leaflet was last updated in March 2018.

This is a Medicament

- Medicament is a product but not like the others.
- 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.

Keep all medicaments out of reach of children



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