

PATIENT INFORMATION LEAFLET

FENTAVER 0.5 mg/10 mL I.V./I.M. Solution for Injection

Sterile

Administered intramuscular and intravenously.

- **Active Ingredient:** Each 1 mL solution contains 0.0785 mg fentanyl citrate equivalent to 0.05 mg fentanyl.
- **Excipients:** Sodium chloride, water for injection.

Read all of this leaflet carefully before you start using 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 pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low doses** other than the recommended dosage.*

What is in this leaflet:

1. *What FENTAVER is and what it is used for?*
2. *What do you need to know before you use FENTAVER*
3. *How to use FENTAVER?*
4. *Possible side effects*
5. *How to store FENTAVER?*

1. What FENTAVER is and what it is used for?

- FENTAVER is a solution that is a powerful pain reliever from the group called “opioid analgesics” and applied intravenously and intramuscularly. Strong pain relief effect of FENTAVER lasts for a short time.
- 1 mL FENTAVER contains fentanyl citrate equivalent to 0.05 mg fentanyl.
- FENTAVER is available in packages containing 1 ampoule of 10 mL.
- FENTAVER is used to prevent or relieve pain that occurs in different types of surgeries. FENTAVER can be used in such surgeries:
 - Short-term surgeries that can be discharged on the day of the operation
 - Longer surgeries that may require you to stay in hospital for several days
- FENTAVER is also used in high doses to reduce your natural breathing rate if you are connected to a ventilator (i.e. if you are being given artificial respiration). In this way, it is used to put you to sleep together with a sedative drug called neuroleptic that makes you sleepy or causes dizziness in major surgeries.

2. What do you need to know before you use FENTAVER

FENTAVER is a strong painkiller and should only be prescribed / administered by authorized persons.
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DO NOT USE FENTAVER;

If:

- You have hypersensitivity (allergy) to fentanyl and any of the excipients (see excipients list) of the drug,
- You have hypersensitivity (allergy) to strong painkillers called 'opioid analgesics',
- You have had a surgical operation in the bile duct, after this procedure,
- In combination with drugs in the group of monoamine oxidase inhibitors used in the treatment of depression or for two weeks after discontinuation of treatment with these drugs,
- You have a respiratory illness that restricts your breathing (obstructive pulmonary disease) or your breathing is compressed; In this case, you can only use FENTAVER if your breathing is supported by a device called a “ventilator”.
- Before clamping the umbilical cord if you are having a normal birth or giving birth by cesarean section; FENTAVER can affect your baby's breathing.

Do not use this medicine if any of the above applies to you. If you are not sure, consult your doctor before using FENTAVER.

USE FENTAVER CAREFULLY;

Consult your doctor before using this medicine.

If:

- You have a problem with your lungs, liver or kidneys.
- You have decreased thyroid (the gland located in the front of the neck) functions (hypothyroidism),
- You have lung disease or respiratory problems,
- You have an alcohol addiction,
- If you have a brain disorder or have recently suffered a brain disorder / injury,
- You have a disease called Myasthenia gravis that causes muscle fatigue,
- You are being treated with strong painkillers for a long time,
- You have a decrease in blood volume,
- You are elderly or weak due to the disease, use this drug carefully.

Conditions requiring special monitoring:

- FENTAVER can cause you to breathe more slowly. If such an effect is seen, your breathing will be closely monitored until it returns to normal.
- Sometimes your blood pressure and heart rate may also need to be monitored.

Repeated use of fentanyl can lead to the development of tolerance, that is, the body's insensitivity to fentanyl and dependence due to frequent use.

When using FENTAVER with drugs that affect the serotonin system, a chemical that allows brain cells to communicate with each other and with other nerve cells, caution is required against the possibility of developing a life-threatening serotonin syndrome.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

If your doctor deems appropriate, you can continue to use FENTAVER.

Use of FENTAVER with food and drink

No information has been given regarding FENTAVER's interaction with food and drink. It should not be used with alcohol. When used with St. John's Wort, its level and effect may decrease.

Pregnancy

Consult your doctor or pharmacist before using this medication.

- If you are pregnant or think you may be pregnant, you can only use FENTAVER if your doctor decides it is absolutely necessary.
- During delivery (including cesarean delivery) fentanyl should not be administered as it may cause respiratory suppression in the newborn.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

FENTAVER passes into milk. Do not breastfeed your baby while using FENTAVER. Do not breastfeed your baby or use expressed breast milk before 24 hours after FENTAVER administration.

Driving and using machines

Do not drive or use machinery for at least 24 hours after taking FENTAVER as you may be less careless than usual.

This medicine may impair your ability to drive as it may cause you to become drowsy, dizzy, or lightheaded. After the application of FENTAVER, do not use tools or machines and do not perform tasks that require attention before sufficient time has elapsed.

Do not drive before learning how the drug will affect you.

It is a traffic offense to drive while under the influence of this medicine; However, if the following applies to you, taking the drug does not knowingly commit a traffic offense:

- This medicine is prescribed for the treatment of a medical illness or dental treatment.
- You are taking the medicine as your prescriber told you and as directed in this "Patient Information Leaflet".
- If it does not affect your ability to drive safely.

After using FENTAVER, always consult your doctor before driving or using machine.

Important information about some of the excipients in FENTAVER

If you need to keep your salt intake under control (if you are on a controlled sodium diet), be careful about the following:

- Since each ampoule of FENTAVER contains less than 23 mg of sodium, no sodium-related side effects are expected.
- However, the contents of the ampoule can be diluted with salt solution before being given to you. For this reason, sodium in the salt solution used in dilution should also be taken into consideration.

Using other medicines

Since many drugs cannot be used with FENTAVER, always inform your doctor if you are taking

any other medication. This is also true for non-prescription or herbal medicines.

Especially do not take the following medicines and tell your doctor or nurse if you have taken in the last two weeks:

- Some drugs called monoamine oxidase inhibitors and used in the treatment of depression (mental depression).

Do not use FENTAVER if you are using this group of drugs.

It is important to talk to your doctor or nurse, especially if you are taking any of the following medicines:

- Drugs such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline and venlafaxine used in the treatment of depression (mental depression).
- If any of the following drugs are taken together with FENTAVER, there may be an increase in the effects of FENTAVER or these drugs:
- Other strong pain relievers such as morphine or codeine called "opioid analgesics" for your pain,
- Medications that make you sleepy (anesthetic agents)
- Medications used to treat anxious situations (anxiety) (tranquilizers) or sleeping pills,
- Medicines such as ritonavir, indinavir or saquinavir, which are used in the treatment of HIV (human immunodeficiency virus, AIDS agent) infection, which are protease inhibitor antivirals,
- Fungicides such as fluconazole or voriconazole,

If you need to take drugs called etomidate and midazolam together with FENTAVER, the dose of these drugs may need to be reduced.

If you are currently using any prescription or non-prescription medicine or have used it recently, please inform your doctor or pharmacist about them.

3. How to use FENTAVER?

FENTAVER should be administered in an environment that only the airway can control and by a person who can control the airway.

Instructions for use and dose/administration frequency:

The amount of FENTAVER to be administered varies depending on the person and the situation. Your doctor will determine how much FENTAVER you should use based on your body weight, general health condition, age, the purpose of this medicine and the other medicines you are using.

Method of administration

FENTAVER is administered by injection into the vein and muscle (intravenous, intramuscular administration).

It can be administered with an anesthetic agent.

It can also be used with some other drugs to alleviate some of the side effects of FENTAVER, such as slowing the heart rate and hardening of the muscles.

The dose of FENTAVER given as an infusion depends on body weight.

As an initial dose, 1 microgram per kilogram per minute can be given for the first 10 minutes.

If necessary, it can be continued with 0.1 micrograms per kilogram every minute of the operation.

Drops are normally 40 minutes after the end of the operation will be terminated first.

Various age groups:

Use in children:

In children between the ages of 2-12, treatment should be started at the doses recommended by the doctor.

FENTAVER should be administered by experienced personnel in environments with the necessary equipment to provide a possible support for breathing.

Use in the elderly:

Lower doses of FENTAVER may be required in elderly or debilitated persons.

Special cases of use:

Renal/Hepatic failure:

FENTAVER doses should be carefully adjusted in patients with impaired kidney and liver function. Your doctor will make this dose adjustment.

If you have an impression that the effect of FENTAVER is too strong or too weak, talk to your doctor or pharmacist.

If you use more FENTAVER than you should

It is unlikely that you will be overdosed, but your doctor will take the necessary precautions. Its main symptom is respiratory depression.

Talk to a physician or pharmacist if you have used more FENTAVER than you should use.

If you forget to use FENTAVER

Since FENTAVER will be administered to you by your doctor, it is unlikely that you will forget to use it.

Do not take double doses to make up for forgotten doses.

Effects that may occur when treatment with FENTAVER is terminated

Your doctor will terminate and monitor the FENTAVER treatment.

4. Possible side effects

As with all medicines, there may be side effects in people who are sensitive to the ingredients of FENTAVER. Your doctor will observe these effects during the administration.

If you notice any of the following, stop using FENTAVER and inform your doctor IMMEDIATELY, or apply to the emergency service of the nearest hospital:

- Swelling of the hands, feet, ankles, face, lips or swelling of the mouth or throat that makes it difficult to swallow or breathe.
- Rash, itching
- Fainting

The frequency of adverse events is reported using the following categories.

Very common : can be seen at least 1 out of 10 patients.

Common : can be seen less than one in 10 patients, but more than one in 100 patients.

Uncommon : can be seen less than one in 100 patients, but more than one in 1,000 patients.

Rare : can be seen less than one in 1.000 patients, but more than one in

Very rare

Very common:

- Common:**

- Uncommon:**

- ## Unknown

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- Itching of the skin,
- Respiratory suppression

Other side effects seen when FENTAVER is administered in combination with drugs called neuroleptics that can be given before or during surgery:

- Shivering and restlessness,
- Seeing objects that are not there (hallucinations),
- Abnormal movements, including tremors and shaking of the hands and fingers, twisting movements in the body, staggering walking and stiffness in the arms and legs.

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store FENTAVER

Keep FENTAVER out of the reach and sight of children and within its packaging.

Store at room temperature under 25 ° C.

FENTAVER is stable for 24 hours at 2-8 ° C when diluted with 0.9% NaCl and 5% Dextrose solution.

Store the ampoules in their original outer carton to protect from light.

Use in compliance with the expiry date.

Do not use FENTAVER after the expiry date which is stated on the packaging.

If you notice any damage on the product and / or package, do not use FENTAVER.

Do not throw away expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder

HAYER FARMA İlaç A.Ş.

Akbaba Mah. Maraş Cad. No:52/2/1

Beykoz / İstanbul / Turkey

Manufacturer:

Osel İlaç Sanayi ve Ticaret A.Ş.

Akbaba Mah. Maraş Cad. No: 52

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