

PATIENT INFORMATION LEAFLET

FENTAVER 0.1 mg/2 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 milligram 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.*

In this Information Leaflet:

1. *What FENTAVER is and what is it used for?*
2. *Things to consider before using the FENTAVER*
3. *How to use FENTAVER?*
4. *What are the possible side effects?*
5. *Storage of FENTAVER*

Headings are included.

1. What FENTAVER is and what is it 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 milligram fentanyl.
- FENTAVER is available in packages containing 10 ampoules of 2 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. Things to consider before using the 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 if you;

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.

Uncommon:

- Changes in blood pressure
- Negativities about breathing,
- Breathing more often than usual
- Body temperature below normal or chills / tremors,
- Headache,
- Swelling or clotting of a vein, phlebitis (inflammation in your veins),
- Hiccups,
- Excessive cheerfulness / happiness,

Unknown

- Difficulty breathing or severe allergic reactions that may lead to dizziness and urticaria.
- Seizures (convulsions),
- Loss of consciousness,
- Tics in the muscles,
- Heart arrest,
- Slow or shallow breathing,
- 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 listed or not listed in this leaflet, talk to your doctor, pharmacist or nurse. Also, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effects Reporting" icon on www.titck.gov.tr or by calling the side effect reporting line at 0 800 314 00 08. By reporting side effects, you can help provide more information on the safety of this medicine.

5.Storage of 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

HAVER FARMA İlaç A.Ş.

Akbaba Mah. Maraş Cad. No:52/2/1 34820

Beykoz / İstanbul

Manufacturer:

Osel İlaç Sanayi ve Ticaret A.Ş.

Akbaba Mah. Maraş Cad. No: 52

Beykoz İSTANBUL

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