

## PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

# Fentamed 100 mcg Fentamed 200 mcg Fentamed 300 mcg Fentamed 400 mcg Fentamed 600 mcg Fentamed 800 mcg

## Sublingual tablets

### Composition:

Each sublingual tablet contains:

The active ingredient and its quantity:

**Fentamed 100 mcg:** fentanyl (as citrate) micronized 100 mcg

**Fentamed 200 mcg:** fentanyl (as citrate) micronized 200 mcg

**Fentamed 300 mcg:** fentanyl (as citrate) micronized 300 mcg

**Fentamed 400 mcg:** fentanyl (as citrate) micronized 400 mcg

**Fentamed 600 mcg:** fentanyl (as citrate) micronized 600 mcg

**Fentamed 800 mcg:** fentanyl (as citrate) micronized 800 mcg

For a list of the inactive ingredients and allergens in the preparation see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar. The medicine is intended for adults over 18 years old.

- Taking this medicine together with benzodiazepine medicines, other medicines that depress the central nervous system (including drugs) or alcohol, may cause a sensation of deep drowsiness, breathing difficulties (respiratory depression), coma and death.
- Medicines from the opioid family may cause addiction, especially with prolonged use, and have the potential for abuse and overdose. A reaction to an overdose can be manifested in slow breathing and even cause death. Make sure you know the name of the medicine, the dosage you are taking, the frequency of administration, the duration of treatment, and the potential side effects and risks. Additional information regarding the risk of dependence and addiction can be found at the link: [https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids\\_en.pdf](https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf)

### 1. What is the medicine intended for?

Fentamed is intended for the treatment of breakthrough pain in oncologic patients who are treated with strong pain relief medicines (opioids) regularly.

Breakthrough pain is pain that occurs suddenly, even though you are using an opioid pain relief medicine regularly.

**Therapeutic class:** the active ingredient in Fentamed sublingual tablets is fentanyl. Fentanyl belongs to a group of strong narcotic pain relief medicines called opioids.

### 2. Before using the medicine

- Do not use this medicine if:**
- You are sensitive (allergic) to the active ingredient, fentanyl, or to any of the other components the medicine contains (listed in section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine").
  - You suffer from severe breathing problems.
  - You are not regularly using an opioid prescription medicine every day at regular times for at least a week to control your persistent pain (e.g., opioid medicines such as: codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine). If you are not using a medicine of this type, you **must not** use Fentamed as the medicine may increase the risk of dangerously slow and/or shallow breathing or cessation of breathing.
  - You suffer from short-term pain that is different from breakthrough pain.
  - You are treated with medicines containing sodium oxybate.

### Special warnings regarding the use of the medicine

Store this medicine in a closed, safe place, where other people cannot access it (for additional information, see section 5 "How to store the medicine").

**Tell your doctor or pharmacist before treatment if you suffer or have previously suffered from the following conditions, as your doctor will need to take this information into account when adjusting your dosage:**

- A head injury, because Fentamed may mask the severity of the injury.
- Breathing problems or if you suffer from muscle weakness disease (myasthenia gravis).
- If you suffer from heart problems, especially if you suffer from slow heart rate.
- Low blood pressure.
- Liver or kidney disease, your doctor may need to adjust the dosage more carefully.
- A brain tumor and/or increased intracranial pressure (increased pressure in the brain causing severe headaches, nausea/vomiting and blurred vision).
- Mouth ulcers or inflammation of the oral mucosa (swelling and redness in the oral cavity).
- If you are taking antidepressants or antipsychotics, please read carefully the next section, "Drug interactions".
- If you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with the use of opioids.

**During the period of treatment with Fentamed, inform the doctor or dentist that you are being treated with this medicine, if:**

- You are about to undergo any surgery.
- You experience pain or increased sensitivity to pain (hyperalgesia) that do not respond to a higher dosage of the medicine as prescribed by the doctor.
- You suffer from a combination of the following symptoms: nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. A combination of these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency, a condition in which the adrenal glands do not produce enough hormones.

### Long-term use and tolerance

This medicine contains fentanyl, which is an opioid medicine. Repeated use of opioid pain relievers may result in the medicine being less effective (you become used to it, which is known as tolerance to medicines). You may also be more sensitive to pain while using Fentamed. This is known as hyperalgesia. Increasing the dosage of Fentamed may help further reduce the pain for a while, but it can also be harmful. If you notice that your medicine becomes less effective, talk to your doctor. Your doctor will decide whether it is better for you to increase the dosage or gradually decrease the use of Fentamed.

### Dependence and addiction

Repeated use of Fentamed may also lead to dependence, abuse and addiction, which may lead to a life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of the amount of medicine you need or how often you need to use it. You may feel that you need to continue using your medicine, even when it doesn't help relieve your pain.

The risk of developing dependence or becoming addicted varies from one person to another. You may be at a greater risk of developing a dependence on or addiction to Fentamed if:

- You or someone in your family has ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
  - You smoke.
  - You have ever had problems with your mood (depression, anxiety or personality disorder) or have been treated by a psychiatrist due to other mental diseases.
- If you notice any of the following signs during the use of Fentamed, this can be a sign that you have become dependent or addicted:
- You need to use the medicine for longer than your doctor has recommended
  - You need to use more than the recommended dosage
  - You are using the medicine for reasons other than prescribed, for example, "to stay calm" or "to help you sleep"
  - You have made repeated, unsuccessful attempts to stop or control the use of the medicine
  - When you stop taking the medicine you feel unwell (for example, nausea, vomiting, diarrhea, anxiety, chills, tremor and sweating), and you feel better once you use the medicine again ("withdrawal effects")

If you notice any of these signs, talk to your doctor to discuss the best treatment pathway for you, including when it is right to stop and how to stop safely.

### Sleep-related breathing problems

Fentamed may cause sleep-related breathing problems, such as sleep apnea (breathing pauses during sleep) and hypoxemia during sleep (low blood oxygen level). The symptoms may be: breathing pauses during sleep, night awakening due to shortness of breath, difficulty staying asleep or increased drowsiness during the day. If you or someone else notices these symptoms, refer to the doctor. The doctor may consider reducing the dosage.

### Drug interactions

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.**

Certain medicines may increase or decrease the effects of Fentamed. Therefore, inform the doctor if you are starting, changing the dosage of or stopping treatment with the following medicines, since the doctor may need to adjust the dosage of Fentamed:

- Antifungal medicines used for treatment of fungal infections, such as ketoconazole or itraconazole.
- Macrolide antibiotics used for treatment of infections, for example erythromycin.
- Antiviral medicines belonging to the family of protease enzyme inhibitors used for treatment of infections caused by viruses, for example ritonavir.
- Rifampin or rifabutin (medicines used for treatment of bacterial infections).
- Carbamazepine, phenytoin or phenobarbital (medicines used for treatment of convulsions/seizures).
- Herbal medicines containing Hypericum perforatum (St. John's Wort).
- Medicines containing alcohol.
- Medicines from the monoamine oxidase enzyme inhibitors (MAOI) class, used for the treatment of severe depression and Parkinson's disease. Inform your doctor if you have taken this type of medicine within the last two weeks.
- Certain types of strong pain relievers, called partial agonists/antagonists, for example buprenorphine, nalbuphine and pentazocine. You may feel symptoms of withdrawal syndrome (such as nausea, vomiting, diarrhea, anxiety, chills, tremors and sweating) while using these medicines.

**Fentamed may increase the anesthetic effect of the following medicines (sedatives) and may also increase the risk of respiratory depression and decrease in blood pressure:**

- Other medicines for relieving severe pain (medicines of the opioid family for the relief of pain or cough)
- Pain relievers for neural pain (gabapentin and pregabalin)
- Medicines for general anesthesia (intended for anesthesia during surgeries)
- Muscle relaxants
- Medicines for sleep induction
- Medicines for treatment of:
  - ▶ Depression
  - ▶ Allergies (sedative antihistamines – H1 blockers)
  - ▶ Anxiety and psychosis (medicines from the group of barbiturates, benzodiazepines, for example, diazepam, medicines for sleep induction or anti-anxiety medicines)
- Medicines containing clonidine (for treatment of hypertension)

The use of Fentamed concomitantly with medicines that make you feel sleepy (sedatives), such as benzodiazepines, increases the risk of drowsiness, breathing difficulties (respiratory depression), coma and may be life-threatening. Therefore, the use of Fentamed together with sedatives should only be considered when there are no other treatment options.

However, if the doctor still decides to use Fentamed together with sedatives, the dosage and duration of treatment should be limited by the doctor.

Please tell the doctor about any sedatives that you are taking, and carefully follow the dosage recommended to you by the doctor. It may be useful to inform your friends or relatives to make them aware of the signs and symptoms mentioned above. Contact the doctor when you experience such symptoms.

The risk of certain other side effects increases if you are taking medicines such as antidepressants or antipsychotics, since drug interactions manifested by mental state changes may occur (for example agitation, hallucinations, coma) as well as other effects such as high fever above 38°C, increased heart rate, unstable blood pressure and heightened reflexes, muscle stiffness, lack of coordination and/or gastrointestinal effects (for example nausea, vomiting, diarrhea). In this case, the doctor will advise you whether Fentamed is suitable for you.

### Using the medicine together with food and drink

Grapefruit juice may increase the risk of side effects of Fentamed; therefore, do not drink grapefruit juice during treatment with Fentamed.

### Use of the medicine and alcohol consumption

Fentamed may cause drowsiness in certain patients. Do not consume alcohol during treatment with the medicine without consulting the doctor, because it may cause excessive drowsiness.

### Pregnancy and breastfeeding

**Do not use Fentamed if you are pregnant**, unless you have been explicitly told otherwise by the doctor, since fentanyl may cause withdrawal symptoms in the newborn and endanger its life.

**Do not breastfeed during treatment with Fentamed** and do not start breastfeeding until at least 5 days have passed since the last dose of Fentamed. Fentanyl can pass into breast milk and may cause drowsiness and respiratory depression in the breastfed baby.

**If you are pregnant or breastfeeding, consult the doctor or pharmacist before using medicines.**

### Driving and operating machinery

Fentamed may harm your mental and/or physical ability to perform potentially dangerous tasks such as driving or operating machinery.

If you feel dizzy, drowsy or have blurred vision while using Fentamed, **do not drive a vehicle or operate machinery**.

### Important information about some of the ingredients of the medicine

#### Fentamed contains sodium

This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

### 3. How should you use the medicine?

Before starting treatment with Fentamed, your doctor will explain to you how to take Fentamed to effectively relieve breakthrough pain.

Before starting the treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using Fentamed, when and how long you should take it, when to refer to your doctor and when you need to stop using it (also see section 2).

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The preparation is intended to be used **only** by you according to your doctor's instructions.

**The preparation must not be used by anyone other than you, as it may pose a serious risk to health, especially in children.**

Fentamed is different from other medicines you may have taken in the past for treatment of breakthrough pain. **Always take Fentamed at the dosage prescribed by your doctor** – this dosage can be different from the dosage of other medicines you have taken **in the past** for treatment of breakthrough pain.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is:

#### Starting treatment – finding the most suitable dosage

For Fentamed to work effectively, the doctor needs to identify the most suitable dosage for treatment of your breakthrough pain. Fentamed is marketed in several dosages. You may need to try different dosages of Fentamed over a number of episodes of breakthrough pain to find the most suitable dosage for you.

Your doctor will help you with this and will instruct you on how to find the most suitable tablet strength.

If you do not feel adequate pain relief after one dose, your doctor may instruct you to take another dose to treat an episode of breakthrough pain.

**Do not take an additional dose unless your doctor instructs you to, as this may result in consuming an overdose.**

Your doctor may instruct you to take a dose that consists of more than one tablet at a time.

**You may do this only if the doctor has explicitly instructed you to.**

Wait at least two hours after taking the last dose of Fentamed and before taking the next dose to treat another episode of breakthrough pain.

**Maintenance dose (continuing treatment) – once you have found the most suitable dosage for you**

Once you and your doctor have found the dose of Fentamed that controls your breakthrough pain, do not take this dose more than four times a day. **A dose of Fentamed may consist of more than one tablet.**

Wait at least two hours after taking the last dose of Fentamed and before taking the next dose to treat another episode of breakthrough pain.

If you think that the dose of Fentamed that you are taking is not controlling your breakthrough pain satisfactorily, inform your doctor, the dose may need to be readjusted. Do not change the dosage of Fentamed, unless the doctor has explicitly told you to do so.

**Do not exceed the recommended dose.**

#### Method of use:

Fentamed is intended for sublingual use. Place the tablet under your tongue where it will dissolve rapidly, and the active ingredient, fentanyl, will be absorbed in the oral mucosa. When absorbed, fentanyl starts to relieve the pain.

**When you suffer from breakthrough pain, take the dose prescribed by your doctor as follows:**

- If your mouth is dry, take a sip of water to moisten it. You can spit out or swallow the water.

- Remove the tablet from the blister pack **immediately** before use as follows:
  - ▶ Separate one of the blister squares by tearing along the dividing lines (keep the remaining blister squares together).
  - ▶ Peel back the edge of the aluminum foil in the direction of the marked arrow and carefully remove the tablet. Do not try to push the tablet through the foil cover, as this may damage it.
- Place the tablet under your tongue as far back as you can until it is completely dissolved.
- Fentamed will dissolve rapidly under your tongue and will be absorbed in order to relieve the pain.

**Do not suck, halve, crush, chew or swallow the tablet.**

**Place the tablet whole under your tongue.**

**Do not drink or eat until the tablet has completely dissolved under your tongue.**

**If you accidentally took a higher dosage:**

- Immediately remove any remaining medicine from your mouth.
  - Tell your caregiver or another person about it.
  - Immediately go to the doctor or to a hospital emergency room and bring the package of the medicine with you. The person accompanying the patient should keep the patient awake by talking to him or by shaking him now and then.
  - An overdose may also cause a brain disorder known as toxic leukoencephalopathy.
- Symptoms of an overdose include:**
- Extreme drowsiness
  - Slow, shallow breathing
  - Coma

If these symptoms occur, call emergency medical assistance immediately. If an adult or a child accidentally took this medicine, refer them immediately to a doctor or to a hospital emergency room and bring the package of the medicine.

Follow the treatment as recommended by the doctor.

### If you stop taking the medicine

If you no longer suffer from breakthrough pain, you can discontinue the use of Fentamed, but you must continue using your regular relief medicine to treat your persistent pain according to your doctor's instructions.

If you suffer from withdrawal effects or are concerned about relieving your pain, you should consult the doctor. The doctor will consider whether you need a medicine to treat the withdrawal effects.

Do not stop taking Fentamed abruptly, unless your doctor has told you to do so. If you want to stop taking Fentamed, consult your doctor first. He will tell you how to do so, usually by gradually reducing the dosage, so that you do not experience unpleasant effects. If you abruptly stop taking Fentamed, you may suffer from withdrawal effects, such as: nervousness, anxiety, palpitations, tremor or sweating.

**Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

### 4. Side effects

As with any medicine, using this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

**If you feel extremely or unusually drowsy, or your breathing becomes slow or shallow, immediately refer to a doctor or go to the nearest hospital to receive urgent treatment (also see section 3 "If you accidentally took a higher dosage").**

**Very common side effects – effects that occur in more than one user out of ten:**

- Nausea

**Common side effects – effects that occur in 1-10 users out of 100:**

- Dizziness, headaches, excessive drowsiness
- Shortness of breath
- Inflammation of the oral cavity, vomiting, constipation, dry mouth
- Sweating, fatigue/tiredness/lack of energy

**Uncommon side effects – effects that occur in 1-10 users out of 1,000:**

- Allergic reactions, tremor, visual disturbances or blurred vision, slowed or accelerated heart rate, low blood pressure, memory loss
- Depression, suspicious thoughts or feeling afraid for no reason, feeling confused, feeling disorientated, feeling anxious/restless/sad, feeling unusually happy (euphoria), mood swings
- Persistent feeling of fullness, abdominal pain, indigestion
- Mouth ulcers, problems with the tongue, pain in the mouth or throat, throat tightness, ulcers in the lips or gums
- Loss of appetite, loss of or change in the sense of taste/smell
- Difficulty falling asleep or sleep disturbances, lack of attention/being easily distracted, lack of energy/weakness
- Skin disorders, rash, itching, night sweats, decreased sensitivity to touch, tendency to bruise easily
- Joint pain or stiffness, muscle stiffness
- Drug withdrawal symptoms (such as nausea, vomiting, diarrhea, anxiety, chills, tremor, sweating), taking an accidental overdose, in men: inability to obtain and/or maintain an erection, general bad feeling

**Side effects with unknown frequency (effects whose frequency has not yet been determined):**

- Swollen tongue, severe breathing problems, falling, flushing, feeling excessively warm, diarrhea, convulsions (spasms), swelling of the hands or legs, seeing or hearing things that do not exist in reality (hallucinations), fever, decreased level of consciousness or loss of consciousness, itchy rash and delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that do not exist in reality, sleep disturbances, nightmares).
- Tolerance to the medicine, dependence on the medicine (addiction), abuse of the medicine (see section 2)

Prolonged use of fentanyl during pregnancy may cause withdrawal symptoms in the newborn which may be life-threatening (see section 2).

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

### Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

### 5. How to store the medicine?

- Avoid poisoning! **Fentamed is a very strong pain relief medicine which may be life-threatening if accidentally taken by a child.** Therefore, this medicine and any other medicine must be kept in a closed and locked place out of the reach and sight of others, including children and/or infants to avoid poisoning. Serious and even fatal harm may be caused to people who may take this medicine accidentally or intentionally when it has not been prescribed for them.
- Do not induce vomiting without an explicit instruction from the doctor.
- **It is recommended to keep this medicine in a locked place.**
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package and the blister. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.
- **How to dispose of unused tablets?** If you have Fentamed tablets that are no longer needed, give them to the nearest pharmacy so that they can be destroyed safely, thus protecting the environment. Do not discard medicines in wastewater or domestic trash.

### 6. Additional information

**In addition to the active ingredient the medicine also contains:**

Mannitol, silicified microcrystalline cellulose, magnesium stearate, croscarmellose sodium.

**What does the medicine look like and what are the contents of the package?**  
Fentamed is a small white sublingual tablet. The tablet comes in a range of different strengths and shapes. Your doctor will prescribe you the strength and number of tablets suitable for you.

Fentamed 100 mcg tablet is a white round tablet

Fentamed 200 mcg tablet is a white oval-shaped tablet

Fentamed 300 mcg tablet is a white triangle-shaped tablet

Fentamed 400 mcg tablet is a white diamond-shaped tablet

Fentamed 600 mcg tablet is a white "D"-shaped tablet

Fentamed 800 mcg tablet is a white capsule-shaped tablet

Fentamed is marketed in packs of 30 tablets. The tablets are packed in blisters.

- **License holder and importer:** Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak.
- **Manufacturer:** Kern Pharma, S.L. Terrassa, Barcelona, Spain.

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**Registration numbers of the medicines in the national drug registry of the Ministry of Health:**

Fentamed 100 mcg 173-43-36706

Fentamed 200 mcg 173-44-36707

Fentamed 300 mcg 173-45-36708

Fentamed 400 mcg 173-46-36709

Fentamed 600 mcg 173-47-36710

Fentamed 800 mcg 173-48-36711