

Package leaflet: Information for the patient

Fenhuma 100 microgram sublingual tablets

Fenhuma 200 microgram sublingual tablets

Fenhuma 300 microgram sublingual tablets

Fenhuma 400 microgram sublingual tablets

Fenhuma 600 microgram sublingual tablets

Fenhuma 800 microgram sublingual tablets

fentanyl

Read all of this leaflet carefully before you start taking 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fenhuma is and what it is used for
2. What you need to know before you take Fenhuma
3. How to take Fenhuma
4. Possible side effects
5. How to store Fenhuma
6. Contents of the pack and other information

Important things you should know about fentanyl:

This medicine contains fentanyl which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

- This product provides a high dose of opioid that can be fatal if not used appropriately

1. What Fenhuma is and what it is used for

This medicine has been prescribed for you for treatment for adults **who must already regularly be taking strong pain-relieving medicine (opioids)** for their persistent cancer pain, but require treatment for their breakthrough pain.

It contains the fentanyl which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Breakthrough pain is pain which occurs suddenly, even though you have taken or used your usual opioid pain-relieving medicine.

2. What you need to know before you take Fenhuma

Do not take Fenhuma

- if you are allergic to fentanyl or any of the other ingredients of this medicine (listed in section 6)
- if you have severe breathing problems

- if you are not regularly using a prescribed opioid medicine (e.g codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine), every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you **must not** use Fenhuma because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop.
- if you suffer from short-term pain other than breakthrough pain.
- if you are being treated with medicines containing sodium oxybate.

Fentanyl is a strong opioid and should not be used unless you have previously been prescribed other opioids.

This particular formulation is highly addictive. Contact your prescriber if you or a family member has concerns regarding use of this medicine.

Warnings and precautions

- Store this medicine in a safe and secure place, where other people cannot access it (see section 5. How to store Fenhuma for more information).

Talk to your doctor or pharmacist before taking Fenhuma if you have or have recently had any of the following, as your doctor will need to take account of these when prescribing your dose:

- a head injury, because Fenhuma may cover up the extent of the injury
- breathing problems or suffer from myasthenia gravis (a condition characterised by muscle weakness)
- if you have problems with your heart, especially a slow heart rate
- low blood pressure
- liver or kidney disease, as this may require your doctor to more carefully adjust your dose
- a brain tumour and/or raised intracranial pressure (an increase of pressure in the brain which causes severe headache, nausea/vomiting and blurred vision)
- mouth wounds or mucositis (swelling and redness of the inside of the mouth)
- if you take antidepressants or antipsychotics please refer to the section 'Other medicines and Fenhuma'
- if you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Fenhuma to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

When taking Fenhuma, inform your doctor or dentist that you are taking this medicine, if:

- you are to have any surgery
- you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine as prescribed by your doctor
- you experience a combination of the following symptoms: nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Together 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 painkillers can result in the drug being less effective (you become accustomed to it, known as drug tolerance). You may also become more sensitive to pain while using Fenhuma. This is known as hyperalgesia. Increasing the dose of Fenhuma may help to further reduce your pain for a while, but it may 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 dose or to gradually decrease your use of Fenhuma.

Dependence and addiction

Repeated use of Fenhuma can also lead to dependence, abuse and addiction which may result in 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 how much medicine you need to use or how often you need to use it. You might feel that you need to carry on using your medicine, even when it doesn't help to relieve your pain. The risk of becoming dependent or addicted varies from person to person.

You may have a greater risk of becoming dependent or addicted on Fenhuma if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illness.

If you notice any of the following signs whilst using Fenhuma, it could be a sign that you have become dependent or addicted.

- You need to use the medicine for longer than advised by your doctor
- You need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell (e.g. nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating), and you feel better once using the medicine again (‘withdrawal effects’)

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

Sleep-related breathing disorders

Fenhuma can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties in maintaining sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Fenhuma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (other than your regular opioid pain-relieving medicine).

Some medicines may increase or decrease the effects of Fenhuma. Therefore, if you start, change the dose of, or stop therapy with the following medication tell your doctor as they may need to adjust your dose of Fenhuma:

- Certain types of antifungal medicines containing e.g. ketoconazole or itraconazole (used to treat fungal infections).
- Certain types of antibiotic medicines called macrolides, containing e.g. erythromycin (used to treat infections).
- Certain types of antiviral medicines called protease inhibitors, containing e.g. ritonavir (used to treat infections caused by viruses).
- Rifampin or rifabutin (medicines used to treat bacterial infections)
- Carbamazepine, phenytoin or phenobarbital (medicines used to treat convulsions/fits).
- Herbal medicines containing St John's wort (*Hypericum perforatum*)
- Medicines containing alcohol
- Medicines called monoamine-oxidase (MAO) inhibitors, which are used for severe depression and Parkinson's disease. Tell your doctor if you have taken this type of medicine within the last two weeks
- Certain types of strong pain killers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines.

Fenhuma may add to the effect of medicines that make you feel sleepy (sedative medicines), including:

- other **strong pain-relieving medicines** (opioid-type medicines e.g. for pain and cough)
- some painkillers for nerve pain (gabapentin and pregabalin)
- general anaesthetics (used to make you sleep during operations)
- muscle relaxants
- sleeping tablets
- medicines used to treat
 - depression
 - allergies
 - anxiety (such as benzodiazepines e.g. diazepam) and psychosis
- medicines containing clonidine (used to treat high blood pressure).

Use of Fenhuma at the same time as medicines that make you feel sleepy (sedative medicines), such as benzodiazepines, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, use of Fenhuma together with sedative medicines should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Fenhuma together with sedative medicines, the dose and duration of treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The risk of certain other side effects increases if you are taking medicines such as certain antidepressants or antipsychotics. Fenhuma may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Your doctor will tell you whether Fenhuma is suitable for you.

Fenhuma with food, drink and alcohol

Fenhuma can make some people feel drowsy. Do not consume alcohol without consulting your doctor as it might make you feel more drowsy than usual.

Do not drink grapefruit juice while you are prescribed Fenhuma treatment as it may increase the side effects of Fenhuma.

Pregnancy and breast-feeding

Pregnancy

Do not take Fenhuma 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 you use Fenhuma during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Fenhuma while you are breastfeeding as fentanyl passes into breast milk and will affect your baby.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant or breast-feeding.

Driving and using machines

Fenhuma may impair your mental and/or physical ability to perform potentially hazardous tasks such as driving or operating machinery.

If you feel dizzy, sleepy or have blurred vision when you take Fenhuma, do not drive or use machinery.

Driving in the UK

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

Do not drive while taking this medicine until you know how this medicine affects you.

It may be an offence to drive if your ability to drive safely is affected by taking this medicine.

There is further information for patients who are intending to drive in the UK - go to <https://www.gov.uk/drug-driving-law>

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Fenhuma contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Fenhuma

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

Your prescriber should have discussed with you; how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Before taking Fenhuma for the first time your doctor will explain how Fenhuma should be taken to effectively treat your breakthrough pain.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This product should **ONLY** be used by you according to your doctor's instructions. It should not be used by anyone else as it could present a **SERIOUS** risk to their health, especially in children.

Fenhuma is a different type of medication from other medicines you may have used to treat your breakthrough pain. **You must always use the dose of Fenhuma as prescribed by your doctor** – this may be a different dose from that which you have used with other medicines for breakthrough pain.

Starting Treatment – Finding the most appropriate dose

For Fenhuma to work successfully, your doctor will need to identify the most appropriate dose for treating your breakthrough pain. Fenhuma is available in a range of strengths. You may need to try different strengths of Fenhuma over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will help you do this and will work with you to find the best dose to use.

If you do not get adequate pain relief from one dose your doctor may ask you to take an extra dose to treat an episode of breakthrough pain. Do not take a second dose **unless your doctor tells you to**, as this may result in overdose.

Sometimes your doctor may advise you to take a dose which consists of more than one tablet at a time.

Only do this if directed by your doctor.

Wait at least 2 hours from taking your last dose before treating your next episode of breakthrough pain with Fenhuma.

Continuing Treatment - Once you have found the most appropriate dose

Once you and your doctor have found a dose of Fenhuma that controls your breakthrough pain you should take this dose no more than four times a day. **A dose of Fenhuma may consist of more than one tablet.**

Wait at least 2 hours from taking your last dose before treating your next episode of breakthrough pain with Fenhuma.

If you think that the dose of Fenhuma that you are using is not controlling your breakthrough pain satisfactorily tell your doctor, as he may need to adjust your dose.

You must not change your dose of Fenhuma unless directed by your doctor.

Taking the medicine

Fenhuma should be used sublingually. This means that the tablet should be placed under the tongue where it dissolves rapidly in order to allow fentanyl to be absorbed across the lining of the mouth. Once absorbed, fentanyl starts to work to relieve pain.

When you get an episode of breakthrough pain, take the dose advised by your doctor as follows:

- If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water.
- Remove the tablet(s) from the blister pack immediately before use as follows.

- Separate one of the blister squares from the pack by tearing along the dotted lines/perforations (keep the remaining blister squares together)

- Peel back the edge of the foil where the arrow is shown and gently remove the tablet. Do not try to push Fenhuma sublingual tablets through the foil top, as this will damage them.
- Place the tablet under your tongue as far back as you can and let it dissolve completely.
- Fenhuma will dissolve rapidly under the tongue and be absorbed in order to provide pain relief. It is therefore important that you do not suck, chew or swallow the tablet.
- You should not drink or eat anything until the tablet has completely dissolved under your tongue.

If you take more Fenhuma than you should

- remove any remaining tablets from your mouth
- tell your carer or another person what has happened
- you or your carer should immediately contact your doctor, pharmacist or local hospital and discuss what action to take
- while waiting for the doctor, keep the person awake by talking to or shaking her/him now and then

Symptoms of overdose include:

- extreme drowsiness
- slow, shallow breathing
- coma

An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

If these occur, seek emergency medical help immediately.

If you think someone has taken Fenhuma by accident seek emergency medical help immediately.

If you stop taking Fenhuma

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

You should discontinue Fenhuma when you no longer have any breakthrough pain. You must however continue to take your usual opioid pain relieving medicine to treat your persistent cancer pain as advised by your doctor. You may experience withdrawal symptoms similar to the possible side effects of Fenhuma when discontinuing Fenhuma. If you experience withdrawal symptoms or if you are concerned about your pain relief you should contact your doctor. Your doctor will evaluate if you need medicine to reduce or eliminate the withdrawal symptoms.

There is a risk that you may become addicted to or dependent on these tablets (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking you tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. If you suddenly stop taking these tablets you may get withdrawal symptoms such as

- agitation,
- anxiety,
- palpitations,
- shaking or
- sweating

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

If you start to feel unusually or extremely sleepy or your breathing becomes slow or shallow, you or your carer should immediately contact your doctor or local hospital for emergency help (see also section 3 “If you take more Fenhuma than you should”).

Very common side effects (may affect more than 1 in 10 people) include:

- nausea

Common side effects (may affect up to 1 in 10 people) include:

- dizziness, headache, excessive sleepiness
- breathlessness/shortness of breath
- inflammation inside the mouth, vomiting, constipation, dry mouth
- sweating, weary/tired/lack of energy

Uncommon side effects (may affect up to 1 in 100 people) include:

- allergic reaction, trembling/shaking, disturbed or blurred vision, fast or slow heart-beat, low blood pressure, memory loss
- depression, suspicious thoughts/ feeling afraid for no reason, feeling confused, feeling disorientated, feeling anxious/unhappy/restless, feeling unusually happy/healthy, mood swings
- feeling full all the time, stomach-ache, indigestion
- mouth ulcers, problems with tongue, pain in mouth or throat, tightness in throat, lip or gum ulcers
- loss of appetite, loss of or change in sense of smell/taste
- difficulty sleeping or disturbed sleep, disturbance in attention/easily distracted, lack of energy/weakness/loss of strength
- abnormality in skin, rash, itchiness, night sweats, decreased sensitivity to touch, bruising easily
- joint pain or stiffness, stiffness in muscles
- drug withdrawal symptoms, (*may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating*), accidental overdose, in males an inability to get and/or keep an erection, feeling generally unwell

Not known: (frequency cannot be estimated from the available data)

- swollen tongue, severe breathing problems, fall, flushing, feeling very warm, diarrhoea, convulsion (fits), swelling of arms or legs, seeing or hearing things that are not really there (hallucinations), fever, drug dependence (addiction) (see section 2), drug abuse (see section 2), drug tolerance (see section 2), reduced level or loss of consciousness, itchy rash and delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares), dependence and addiction (see section “How do I know if I am addicted?”).

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

Drug Withdrawal

When you stop taking Fenhuma, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Fenhuma, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Fenhuma

The pain-relieving medicine in Fenhuma is very strong and could be life-threatening if taken accidentally by a child. Fenhuma must be kept out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

It is recommended to keep Fenhuma in a locked storage space.

Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

Any unused product should be taken, if possible, to your pharmacist to be disposed of safely. Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What Fenhuma contains

The active substance is fentanyl. One sublingual tablet contains:

- 100 micrograms fentanyl (as citrate)
- 200 micrograms fentanyl (as citrate)
- 300 micrograms fentanyl (as citrate)
- 400 micrograms fentanyl (as citrate)
- 600 micrograms fentanyl (as citrate)
- 800 micrograms fentanyl (as citrate)

The other ingredients are mannitol (E421), silicified microcrystalline cellulose, croscarmellose

sodium and magnesium stearate.

What Fenhuma looks like and contents of the pack

Fenhuma is a small white sublingual tablet to be inserted under the tongue. It comes in a range of different strengths and shapes. Your doctor will prescribe the strength (shape) and number of tablets suitable for you.

The 100 microgram tablet is a 6 mm white round tablet

The 200 microgram tablet is a 7 x 4.5 mm white oval-shaped tablet

The 300 microgram tablet is a 6.2 x 6.2 mm white triangle-shaped tablet

The 400 microgram tablet is a 8.5 x 6.5 mm white diamond-shaped tablet

The 600 microgram tablet is a 8.5 x 6 mm white “D”-shaped tablet

The 800 microgram tablet is a 10 x 6 mm white capsule-shaped tablet

Fenhuma 100, 200, 300 and 400 is available in perforated or non-perforated blisters in cartons of 10, 10 x 1, 30 and 30 x 1 tablets.

Fenhuma 600 and 800 is available in perforated or non-perforated blisters in cartons of 30 and 30 x 1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

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