

Fenhuma[®]

(fentanyl citrate) sublingual tablet

Patient and Carer Guide

Important risk minimisation information
for patients and their carers

Introduction

Patient and carer guide to Fenhuma® (fentanyl citrate) sublingual tablet

Dear Patients/ Carers,

This brochure will provide you with information on how to properly use Fenhuma®. Please familiarise yourself with this important brochure and make sure you have read the Patient Information Leaflet (PIL) in the package of your prescribed medicine or that your carer has read these documents to you. In case of questions or doubts please contact your doctor, pharmacist or nurse.

If you experience any side effects, please tell your doctor, pharmacist or nurse. This also applies to any adverse reaction not mentioned in the information leaflet. You can also report adverse events directly to your local health authority or send an email to medical_information@glenmarkpharma.com. By reporting an adverse reaction, you are contributing to a better understanding of product safety.

You can get a copy of this brochure
by scanning this QR code or from your doctor or pharmacist.



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- **What is Fenhuma® and what is it used for:**

Fenhuma® is a medication containing fentanyl used only for the management of breakthrough pain in adults who are already receiving other opioid pain-relieving medicine (background opioid therapy) for chronic cancer pain. Fenhuma® is a sublingual tablet (administered under the tongue).

- **What is different about cancer pain?**

For people with cancer, pain affects their quality of life and must be treated. Pain can be caused by the cancer itself, by cancer treatments, or by other cancer-related problems. Some pain may have nothing to do with cancer.

- **What is breakthrough pain?**

Some people with cancer experience constant pain which is managed by a doctor with daily pain medicines to keep the pain level low. This pain is called 'background pain'. Sometimes the pain suddenly becomes more severe for a short time, and can prevent the carrying out of normal daily activities. This severe pain is called 'breakthrough pain'.

- **How do I know if I have breakthrough pain?**

Breakthrough pain usually:

- comes quickly (it takes only a few minutes to peak)
- lasts for a relatively short time (about 30 minutes)
- is usually described as moderate to severe
- is often unpredictable (but can also be predictable, triggered by movement such as walking, coughing, sneezing, swallowing, urination, defecation, body care or during medical procedures).

If the background pain is not well controlled or is unstable, the pain experienced is not breakthrough pain.

- **What to do if I have breakthrough pain?**

People with breakthrough pain often need fast-acting strong painkillers, such as Fenhuma®, that work in a few minutes to bring quick relief. They are used in addition to the medications already taken to treat background pain.

- **How to talk with my physician about my cancer pain?**

Differentiating between background pain that is unstable, or not properly managed, and breakthrough pain can be difficult. If you have pain that is not controlled with your current pain medication, contact your doctor. You may be experiencing breakthrough pain or your doctor needs to check whether your pain medications for your background pain are still effective and suitable for you. Your doctor may provide you with pain charts with numbers and images or questionnaires to be able to assess your pain and find the right treatment for you.

It is advisable to take note of your pain episodes to be able to properly describe them. The following are tips to document your pain:

- Where is the pain?
- When did the pain start?
- How often does the pain occur?
- How intense is the pain?
- How long does the pain last?
- What causes the pain to reduce or increase?

Chapter

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Benefits and Risks

- **Why is it important to follow the advice of your physician about Fenhuma®?**

Fenhuma® is a very powerful medication that when used wrongly could lead to serious side effects such as an overdose that could lead to death.

- **Why is it important not to use or switch two different fentanyl medications at the same time?**

This can lead to drug overdose which in turn leads to serious side effects and death. Please speak to your doctor before starting or switching Fenhuma®, especially if you are already on a medication that contains fentanyl (e.g. fentanyl patch).

- **What are some potential side effects of Fenhuma®?**

Potential adverse effects can be seen in the patient information leaflet inside the medicine box or package. Some of the side effects include constipation, drowsiness, dizziness, headaches, throat irritation, nausea, vomiting, hot flush, and misuse (which can lead to serious problems such as addiction, overdose and death).

- **How to reduce the risks of pain medication?**

People with cancer often take many pain medications which all have certain side effects. Your doctor and pharmacist can explain the best way for you to use these pain medications to reduce the risks.

- **When should I worry about overdose, misuse, abuse, dependence, or addiction to opioids?**

Patients taking Fenhuma® may experience overdose, misuse, abuse, dependence or addiction to opioids. Talk to your doctor or pharmacist if you are experiencing the following signs:

Overdose: taking a dose that is higher than the dose recommended by your doctor/pharmacist or in the patient information leaflet of Fenhuma®. Fenhuma® overdose may cause dizziness, breathing difficulties, and may cause the heart to stop leading to death.

Misuse: taking Fenhuma® differently from how it has been prescribed. This includes taking more Fenhuma® than was prescribed, taking Fenhuma® to treat a different problem or symptom such as for the purpose of seeking effects other than pain relief; or taking Fenhuma® prescribed to someone else. Misuse of Fenhuma® may increase the risk of the side effects.

Abuse: the intentional and non-therapeutic use of Fenhuma® with the aim of achieving the desired psychological or physiological effect. Drug abuse may occur continuously or in episodes and is associated with continued use despite worsening physical and/or mental health.

Dependence: refers to physical or psychological dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs after abrupt discontinuation such as excessive sweating, nausea, vomiting, and sleeping difficulties. Psychological dependence refers to a state in which individuals have impaired control over drug use based on the rewarding properties of the drug.

Addiction: chronic and recurrent use of a drug with loss of control (e.g., not able to stop taking it when you want to, having intense cravings for it even when the pain is under control).

Ask your physician or pharmacist if you are concerned by any of the above-mentioned situations.

- **What to do if an overdose is suspected**

Your doctor or pharmacist should train you and your caregiver on how to use the drug naloxone which counters the effect of opioids such as Fenhuma®. It is important to note that the effect of naloxone is short and one might still be in danger after administering naloxone. Call an ambulance for immediate medical assistance.

- **How to avoid problems of misuse, abuse, dependence or addiction when using Fenhuma®?**

Some people may be at a higher risk of experiencing problems when using Fenhuma®. These include people who:

- Have a personal or family history of substance abuse including alcohol abuse
- Have a history of mental health disorders e.g. major depression, anxiety and personality disorders
- Smoke
- Have pre-existing medical conditions such as mood disorder, depression, anxiety and personality disorders.

If you fall into the above-mentioned risk category, tell your doctor. Your doctor will help you manage your pain and use of Fenhuma® appropriately.

- **The best way to prevent the risk of misuse or abuse of Fenhuma®?**

- Use the dose monitoring card that can be seen at the end of this brochure to keep track of the use of your Fenhuma®.
- Contact your doctor immediately if your pain is not under control or if you have any concerns about your symptoms or medications.

- **How to talk with my physician about adverse effects, in particular the risk of misuse, abuse, dependence, or addiction associated with Fenhuma®?**

- First, remember that your doctor is there to help you relieve your pain and address your concerns about your medications. Your doctor will not judge you. Even small concerns need to be addressed.
- Talk with your doctor about how all your medications can work together to better manage your pain.

- Be open and honest about your side effects. Remember that the goal will always be to relieve your pain with as few side effects as possible.
- Don't be afraid or ashamed to ask questions. Your pain is unique, as is your treatment.
- Keep asking questions until you are sure you know how to use your Fenhuma® correctly.
- Ask a trusted relative/friend to accompany you if you fear that you won't understand or remember all the explanations of your physician or pharmacist.

DON'T FORGET

There is no harm in asking for help. Your doctor or pharmacist can advise you, and you can always seek medical treatment for your cancer pain.

Chapter

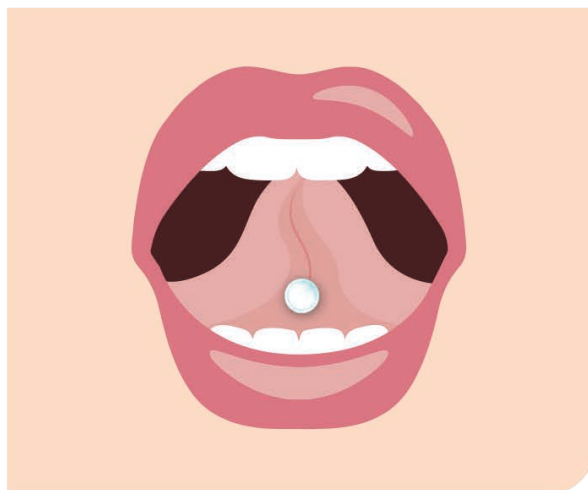
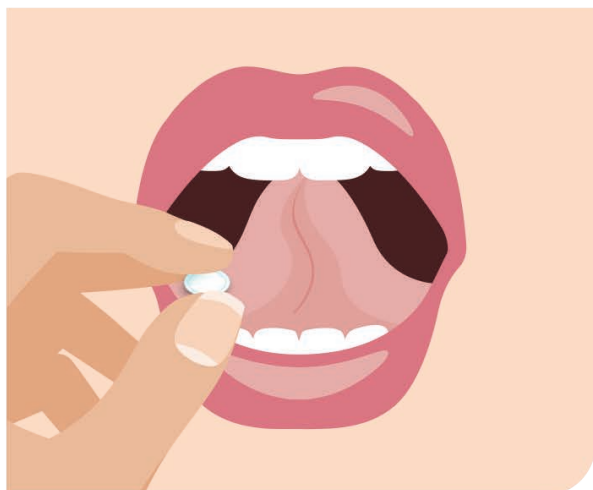
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How to use Fenhuma®

Administration of Fenhuma®

Fenhuma® is a very strong painkiller and must never be taken by anyone but the person it is prescribed for.

- If your mouth is dry, sip some water before taking Fenhuma®.
- Place the Fenhuma® tablet under your tongue, as far back as you can, and let it dissolve completely.
- Do not bite, chew, suck, or swallow the tablet or it will not work properly.
- Do not eat or drink anything until the tablet has completely dissolved.



NB. For more information on how to take Fenhuma®, please read the “Patient Information Leaflet” which can be found in the Fenhuma® pack.

Dosage and Titration

Before taking Fenhuma® for the first time your doctor will explain how Fenhuma® should be taken to effectively treat your breakthrough pain. Fenhuma® is available in a range of strengths. Your doctor may prescribe different strengths of Fenhuma® over several episodes of breakthrough pain to find the most appropriate dose. Your doctor will instruct you what to do. A single dose may involve taking more than one Fenhuma® tablet at any one time. The different strength tablets are different shapes and come in colour-coded boxes to avoid confusion (see below). Your doctor or pharmacist can advise you about these.



Initial dose

The starting dose of Fenhuma® is 100 micrograms (mcg) in all cases, titrating upwards as shown in the table below. You should be monitored during the titration process. Fenhuma® is a generic version of the reference product of Fentanyl sublingual tablets and has demonstrated bioequivalence to the reference product. This means that Fenhuma® is considered interchangeable with the reference product. The initial dosing applies even for patients switching from other fentanyl-containing products for their cancer breakthrough pain (CBTP).

Titration

*During titration, if adequate analgesia is not obtained within 15-30 minutes, a supplemental tablet may be administered.

		First Tablet	Supplemental Tablet
<div>Decrease dose if undesirable effects are unacceptable</div> <div>Increase dose if adequate analgesia is not obtained</div>	Starting Dose	100mcg	100mcg
	Next BTP Episode	200mcg	100mcg
	Next BTP Episode	300mcg	100mcg
	Next BTP Episode	400mcg	200mcg
	Next BTP Episode	600mcg	200mcg
	Next BTP Episode	800mcg	No supplemental tablet

Once an appropriate dose has been established, which may be more than one tablet, patients should be maintained on this dose.



- During titration, you can be instructed to use multiples of 100 microgram tablets and/or 200 microgram tablets for any single dose.
- The total dose for a single episode of BTP during the titration phase includes the first tablet(s) taken plus the supplemental tablet(s), if required.
- No more than four (4) tablets should be used at any one time.
- No more than 4 episodes of BTP should be treated in any 24 hour period, once the dose of Fenhuma® that controls the BTP has been reached.
- If adequate analgesia is achieved at the higher dose, but undesirable effects are considered unacceptable, for the next BTP episode your doctor or other healthcare professional may advise administration of an intermediate dose (using the 100 microgram tablet where appropriate).
- To minimise the risk of opioid-related adverse reactions and to identify the appropriate dose, it is imperative that patients be monitored closely by healthcare professionals during the titration process.

Your doctor or other healthcare professional will monitor you closely whilst finding the best dose for you, to minimise the risk of adverse reactions.

Once you and your doctor have found a dose of Fenhuma® that controls your breakthrough cancer pain you should take this dose no more than four times a day. You should wait at least 2 hours before treating another episode of BTP with Fenhuma®.

Fenhuma® is different to other medicines you may have used to treat your breakthrough pain. You must always use the dose of Fenhuma® prescribed by your doctor – this may be different from that which you have used with other medicines for breakthrough pain, even when those medicines contain fentanyl.

If you are not getting enough pain relief for your breakthrough cancer pain episode, this might indicate that your Fenhuma® dose needs adjusting. Do not attempt to change the dose of your medication yourself. If you experience any problems you should consult your healthcare provider immediately.

Discontinuation

Your pain will be monitored and re-evaluated when renewing prescriptions or during your doctor's visits. Fenhuma® should be discontinued immediately if you no longer experience CBTP episodes. The treatment for the persistent background pain should be continued. If discontinuation of all opioid therapy is required, you will be closely monitored to avoid the possibility of abrupt withdrawal effects. Please discuss with your doctor the option to discontinue treatment with Fenhuma®.

Storage/Safety Information and Disposal of Fenhuma®

How to store Fenhuma®?

Fenhuma® contains an active substance in an amount that can be fatal to a child, therefore it is important to keep all tablets out of the reach and sight of children.

- Fenhuma® should be kept in a locked storage place away from other people.
- Do not store Fenhuma® above 25 degrees.
- Fenhuma® should be kept in the blister packet and not in a pill box.
- Do not use Fenhuma® beyond the expiry date printed on the packaging.

Fentanyl, the active ingredient of Fenhuma®, is a target for people who abuse narcotic medicines or other street drugs and therefore storage instructions must be closely followed. Please also see "How to dispose of Fenhuma®" below.

How to dispose of Fenhuma®?

- Do not dispose of this medication through household waste. To prevent theft, diversion of the drug and misuse, Fenhuma® should always be stored in a suitable safe place.
- Any unused or expired Fenhuma® tablets should be returned to your pharmacist where they will be disposed of in accordance with national and local requirements.

Dose monitoring card (can be found at the end of this brochure)

- This dose monitoring card serves to keep a record of how many Fenhuma® doses you have taken. Remember, it is not safe to treat more than four breakthrough pain episodes per day.
- Remember to fill in the correct dose strength in the dose monitoring card.
- Each time you take Fenhuma®, make sure you or your carer fill it in the card with the date and time Fenhuma® was taken.
- Always take the card to your doctor's visit. The information you record will help your doctor provide you with the best pain treatment.
- If you cannot use the dose monitoring card, make sure to use other means to keep a record of your Fenhuma® use. Ask a friend or carer for help. If necessary, inform your doctor or pharmacist. This will help you find a way to keep track of your Fenhuma® use.

Please report side effects to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google PlayStore

Alternatively you can report a side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to medical_information@glenmarkpharma.com.

Useful Contact Details

Make a note below of who to contact in case you have any questions about your Fenhuma[®] treatment, for example, your doctor's telephone number.

Doctor's name & phone number

.....

Hospital or Practice

.....

Pharmacy's name /phone number.....

.....

Emergency telephone.....

Other

The Fenhuma[®] **patient information leaflet** as contained in the package
can be requested from medical_information@glenmarkpharma.com,
downloaded from <https://www.medicines.org.uk/emc/files/pil.13972.pdf>,
or by scanning the QR code below.



Notes

Fenhuma® Dose Monitoring Card

100/200/300/400/600/800 micrograms (mcg)
sublingual tablets

[illegible]

