

**Fenhuma™**

(sublingual fentanyl citrate tablet)

**Patient & Carer Guide**

**Important risk  
minimisation information for  
patients and their carers**

# Contents

|  |    |
|--|----|
| What is breakthrough cancer pain?                    | 3  |
| What is Fenhuma™?                                    | 4  |
| Starting Fenhuma™ and finding the right dose for you | 6  |
| Once you've found the right dose                     | 7  |
| How to take Fenhuma™                                 | 8  |
| Adverse effects which might be experienced           | 9  |
| Breastfeeding  | 11 |
| Requirements for storing Fenhuma™                    | 12 |
| Learning more – frequently asked questions           | 13 |
| Useful contact details                               | 15 |

## What is breakthrough cancer pain?

Many people who are suffering from cancer will experience regular pain. This ongoing and continuous pain is sometimes called “background pain”. However, people that experience background pain may also experience periods of particularly severe and intense pain that “breaks through” the regular or background pain. This is known as breakthrough cancer pain (BTcP).

Breakthrough cancer pain usually:

- Comes on very quickly
- Is severe and intense, “breaking through” your background pain relief medication
- Rarely lasts more than 30 minutes
- Is not controlled by normal background pain medication
- Can be predictable or unpredictable (and it can be brought on by activities such as walking, coughing or sneezing)

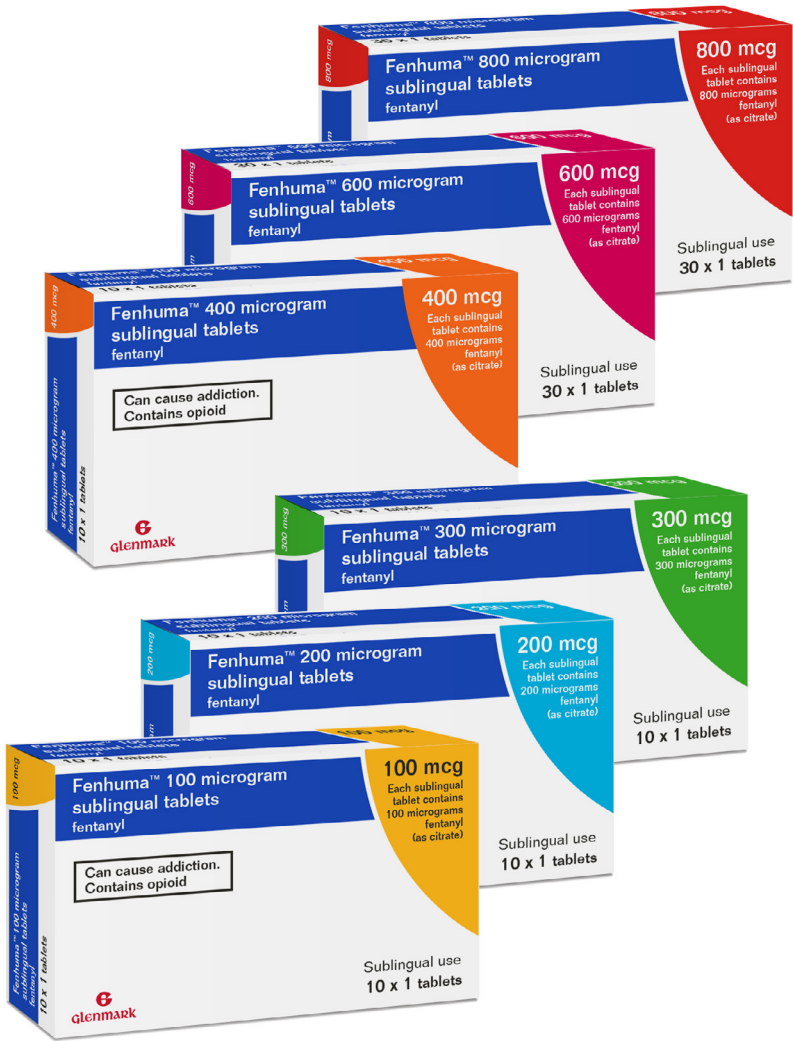
Because breakthrough cancer pain comes on so quickly and is very intense, it needs a specially designed medicine to tackle the pain, which is different to your background cancer pain medicine. The medicines for breakthrough pain are fast-acting and provide pain relief which lasts for about the same amount of time as an episode of breakthrough pain.

The experience of pain is different for everyone. It is therefore very important that you talk to the doctors and nurses looking after you, so that they can find the right type and dose of painkillers to control the type of pain you are experiencing.

You shouldn't feel worried about saying that your pain is not properly controlled. Your doctors and nurses are there to help you.

## What is Fenhuma™?

- Fenhuma™ contains a drug called fentanyl. This is a treatment for adults who must already be taking strong pain-relieving medicine (opioids) for their persistent cancer pain, but require treatment for their breakthrough cancer pain
- Fentanyl is a strong opioid analgesic and may be stronger than the ones you are already taking
- Fenhuma™ is only to be used for breakthrough cancer pain. Fenhuma™ must not be used for other short-term pain. If you are not sure, talk to your doctor
- Fenhuma™ comes in a tablet form that must be allowed to dissolve under your tongue to work. It will dissolve quickly, and has been proven to provide pain relief as early as 10 minutes after taking it. Fenhuma™ has also been shown to provide pain relief over 60 minutes
- It is important that you remain on the medicine (opioids) that you are already taking to control your regular cancer pain
- Your doctor will tell you whether Fenhuma™ is suitable for you
- Fenhuma™ 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 for children
- You should read the Patient Information Leaflet before you start taking Fenhuma™ to make sure it is right for you. Please see the section on page 8 of this booklet called How to take Fenhuma™ for a detailed description of how to take your medicine

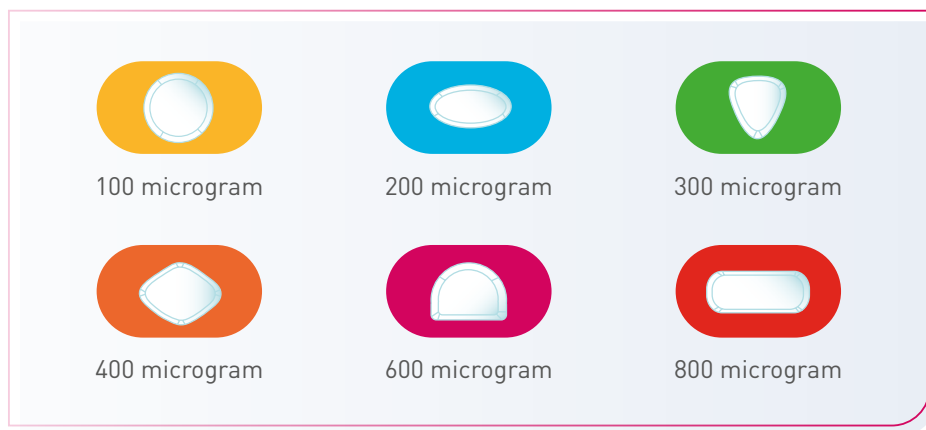


## Starting Fenhuma™ and finding the right dose for you

Before you take 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. 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 instruct you on what to do. A dose may involve taking more than one Fenhuma™ tablet at a time.

The different strength tablets are different shapes and come in colour-coded boxes to avoid confusion. Your doctor or pharmacist can advise you about these.



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

## Once you've found the right dose

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 must leave **at least 2 hours** between doses of Fenhuma™.

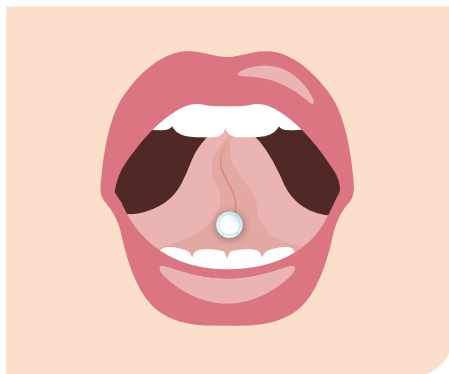
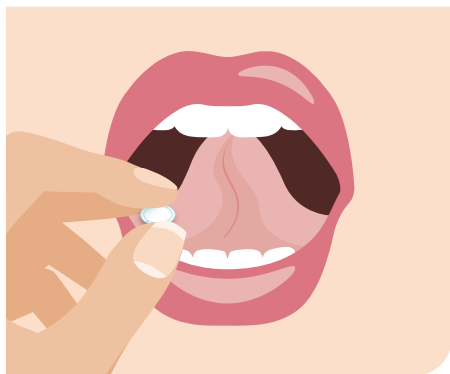
Fenhuma™ is different to other medicines you may have used to treat your breakthrough pain. You must always use the dose of Fenhuma™ prescribed by your doctor – this may be different from your experience with other medicines for breakthrough pain.

Continue to use other opioid medicines for your background pain. Fenhuma™ is only for breakthrough pain.

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.

## How to take 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 your Fenhuma™ pack.



## Adverse effects which might be experienced

- As with other similar pain medicines, Fenhuma™ can cause some side-effects and does carry a risk of accidental overdosing and a risk of abuse. Your healthcare provider should inform you how to minimise these risks
- Fenhuma™ has similar side-effects to those associated with your strong pain-relieving medicine (opioids) for cancer pain. More information on these is detailed in the package leaflet. Your healthcare provider can inform you how to minimise the risks of experiencing side-effects
- If you have not been regularly taking or using a prescribed opioid medicine to control your persistent pain, Fenhuma™ could cause severe breathing difficulties. 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 start to feel unusually drowsy, or your breathing becomes shallow and/or slow, you or your carer should contact your doctor or local hospital immediately
- Fenhuma™ 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 to children

Inform your doctor if 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.

Tolerance and physical and/or psychological dependence may develop upon repeated administration of opioids such as fentanyl. Repeated use of Fenhuma™ may lead to Opioid Use Disorder (OUD). Abuse or intentional misuse of Fenhuma™ may result in overdose and/or death.

## Adverse effects which might be experienced

If you follow the instructions on how to take Fenhuma™, and follow the advice of your healthcare provider on how many Fenhuma™ tablets to take, it is extremely unlikely that you will take too much.

However, in the unlikely event of an overdose you may feel very drowsy or may feel short of breath with only slow or shallow breathing. In the event of an overdose take the following steps:

- **Immediately remove any remaining tablet(s) from your mouth**
- **Tell someone nearby (another person in your house or your nurse/ carer) what has happened**
- **Immediately contact your designated healthcare provider or other emergency medical help**
- **Your nurse/carer should keep you awake by talking to you or shaking you gently while you wait for medical help**

**If you think someone has taken Fenhuma™ by accident, seek emergency medical help immediately by calling 999.**

Please remember to tell your doctor or pharmacist about any medicines you are taking, as they will be able to assess these risks and will decide whether Fenhuma™ is suitable for you. Certain medicines, including some painkillers, may reduce the effects of Fenhuma™. Do not consume alcohol without consulting your doctor. Refer to the patient leaflet for further information.

### Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in the package leaflet. You can also report side-effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>.

By reporting side-effects you can help provide more information on the safety of this medicine.

# Breastfeeding

## **Breastfeeding**

Fentanyl can get into breast milk and may cause side-effects in the breastfed infant. Do not use Fenhuma™ if you are breastfeeding.

You should not start breastfeeding within 5 days after the last dose of Fenhuma™.

## Requirements for storing 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°C



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



Any unused or expired Fenhuma™ tablets should be returned to your pharmacist. Do not dispose of this medication through household waste

It is important to keep Fenhuma™ in a secure place in order to prevent theft, diversion (misuse for illegal purposes) or other misuse. Fentanyl, the active ingredient in Fenhuma™ is a target for people who abuse narcotic medicines or other street drugs.

## Learning more – frequently asked questions



### **Q. When should I take Fenhuma™?**

A. Take Fenhuma™ as soon as an episode of breakthrough cancer pain begins.



### **Q. How quickly does Fenhuma™ work?**

A. Fenhuma™ has been shown to provide pain relief as early as 10 minutes.



### **Q. What should I do if I experience any side-effects when taking Fenhuma™?**

A. If you experience any side-effects when taking Fenhuma™, you should speak to your doctor or nurse who may be able to resolve them while still controlling your breakthrough cancer pain.

Additionally, if you start to feel unusually sleepy, or if your breathing becomes slow or shallow, you or your carer should immediately contact your doctor or local hospital for emergency help.



### **Q. What is the maximum number of breakthrough cancer pain episodes I can treat with Fenhuma™ in a single day?**

A. 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 in any 24 hour period.



## Learning more – frequently asked questions



**Q. How long should I leave between treating episodes of breakthrough pain?**

A. It is important to leave at least 2 hours before treating another episode of breakthrough pain.



**Q. What should I do if I take an overdose?**

A. If you think you have taken an overdose of Fenhuma™, immediately contact your local hospital for emergency help.



**Q. What should I do if I accidentally swallow Fenhuma™?**

A. If you swallow your Fenhuma™ tablet instead of allowing it to dissolve under your tongue, do not take another tablet to replace it during that breakthrough cancer pain episode. You should consult your doctor or nurse for advice.



**Q. What should I do if I am still experiencing breakthrough cancer pain?**

A. You should consult your doctor or nurse for advice.



**Q. Are other medicines available to help control my breakthrough cancer pain?**

A. There are a range of medicines available for controlling breakthrough cancer pain. Your doctor or nurse will be able to advise you about the most effective medicine for your needs.



## Useful contact details

If you have any questions about Fenhuma™ or your pain management, please contact your health professional.

Doctor: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone: \_\_\_\_\_

Nurse: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Please consult the Patient Information Leaflet (PIL) in the Fenhuma™ product package. The PIL is also available for electronic download at [www.mhra.gov.uk](http://www.mhra.gov.uk).











