

Abstral (fentanyl citrate) sublingual tablet

Patient/Carer Guide

This guide provides important information on how to minimise risks when using the fentanyl sublingual tablet

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INTRODUCTION

Dear Patients/ Carers,

This brochure will provide you with information on how to properly use Abstral. 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 side effect not mentioned in the information leaflet. You can also report side effects directly to your local health authority or send an email to drugsafety.IE@grunenthal.com. See page 10 on how to report side effects to the national reporting system or to the company. By reporting side effects, you are contributing to a better understanding of product safety.

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



www.grunenthalhealth.ie/fentanyl-rmm

Chapter 1: Cancer and Pain

What is Abstral and what is it used for?

It is a treatment for adults who are already regularly taking strong pain-relieving medicine (opioids) for their persistent cancer pain but require treatment for breakthrough pain.

The active substance in Abstral is fentanyl. Fentanyl belongs to a group of strong pain-relieving medicines called opioids.

It is a sublingual tablet (administered under the tongue).

What is breakthrough cancer 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 and intense for a short time, even though usual opioid pain-relieving medicine has been taken, 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 on quickly (within minutes),
- lasts for a relatively short time (about 30 minutes),
- is usually described as severe and intense,
- 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 fentanyl sublingual tablets, that work in a few minutes to bring quick relief. They are used in addition to the medications already taken to treat background pain.

Chapter 2: Benefits and Risks

Why is it important to follow the advice of your physician about the fentanyl sublingual tablet?

Fentanyl sublingual tablet is a very powerful medication that when used incorrectly could lead to serious side effects such as an overdose that could lead to death.

Why is it important not to use 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 to Abstral, especially if you are already on a medication that contains fentanyl (e.g. fentanyl patch).

What are some potential side effects?

Potential side effects are listed in section 4 of 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 fentanyl sublingual tablets 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 or in the patient information leaflet. Fentanyl overdose may cause dizziness, breathing difficulties, and may cause the heart to stop leading to death.

Misuse: taking Abstral differently from how it has been prescribed. This includes taking more tablets than prescribed, taking the tablets to treat a different problem or symptom such as for the purpose of seeking effects other than analgesic effect; or taking the tablets prescribed to someone else. Misuse of this medicine may increase the risk of the side effects.

Abuse: refers to the intentional and non-therapeutic use of the medicine 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

If you take more fentanyl sublingual tablets 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.

If these occur, seek emergency medical help immediately. If you think someone has taken these tablets by accident, seek emergency medical help immediately.

How to avoid problems of misuse, abuse, dependence or addiction when using the tablets?

Some people may be at a higher risk of experiencing problems when using the fentanyl sublingual tablets. 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 disorder.

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

The best way to prevent the risk of misuse or abuse of the tablets?

- Use the dose monitoring/count card that can be seen at the end of this brochure to keep track of the use of your medicine.
- 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 the fentanyl sublingual tablets?

- 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 the tablets correctly.
- Ask a trusted relative 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 3: How to take Abstral

Starting the fentanyl sublingual tablet and finding the right dose for you

Before taking these tablets for the first time your doctor will explain how they should be taken to effectively treat your breakthrough pain. The tablets are available in a range of strengths. Your doctor may prescribe the different strengths 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 fentanyl tablet at any one time. Only do this if directed by your doctor.

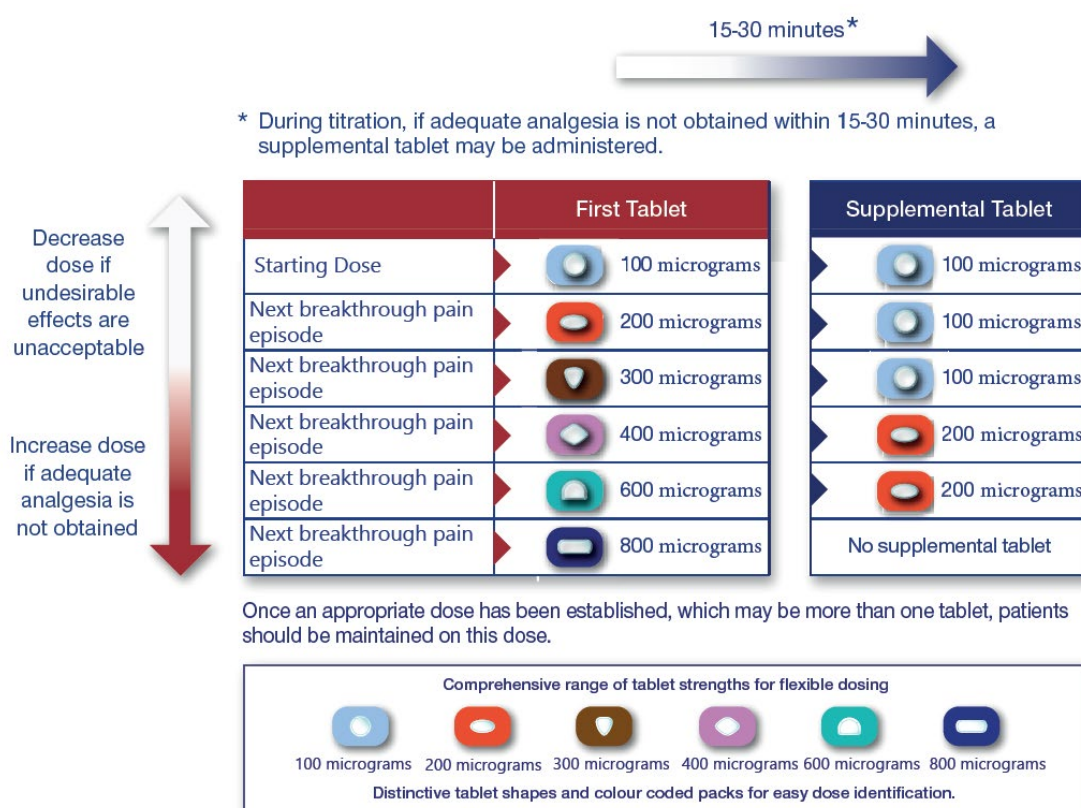
The different strength tablets are of different shapes and come in colour-coded boxes to avoid confusion (see below). Your doctor or pharmacist can advise you about these.



Initial dose

For the fentanyl sublingual tablets to work successfully, your doctor will need to identify the most appropriate dose for treating your breakthrough pain. You may need to try different strengths of the tablets over a number of episodes of breakthrough pain to find the most appropriate dose. You should be monitored during the titration process.

Titration



- During titration, you can be instructed to use multiples of 100 microgram tablets and/or 200 microgram tablets for any single dose.

- Sometimes your doctor may advise you to take a dose which consists of more than one tablet at a time. The total dose for a single episode of breakthrough pain during the titration phase includes the first tablet(s) taken, plus the supplemental tablet(s), if required.
- Once you and your doctor have found a dose that controls your breakthrough pain you should take this dose no more than four times a day.
- No more than 4 episodes of breakthrough pain should be treated in any 24-hour period, once the dose of the fentanyl sublingual tablets that controls the breakthrough pain has been reached.
- If adequate pain relief is achieved at the higher dose, but side effects are considered unacceptable, for the next breakthrough pain 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 side effects and to identify the appropriate dose, you may be monitored closely by health 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.

Opening the pack

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 the sublingual tablets through the foil top, as this will damage them.

Taking the tablets

The fentanyl sublingual tablet 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 the tablet.
- Place the 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 Abstral, please read the "Patient Information Leaflet" which can be found in your product pack.

Once you have found the right dose

Once you and your doctor have found a dose 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 breakthrough pain with these fentanyl sublingual tablets.

Abstral is different to other medicines you may have used to treat your breakthrough pain. You must always use the dose 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 the 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.

Do not take these tablets if you suffer from short-term pain other than breakthrough pain.

Discontinuation

Your pain will be monitored and re-evaluated when renewing prescriptions or during your doctor's visits. The fentanyl sublingual tablets should be discontinued immediately if you no longer experience cancer breakthrough pain 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 the treatment with this medicine.

Chapter 4: Storage and disposal

How to store this medicine?

The tablet 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.

- The fentanyl sublingual tablets should be kept in a locked storage place away from other people.
- Do not store this medicine above 25 degrees.
- The tablets should be kept in the blister packet and not in a pill box.
- Do not use the product beyond the expiry date printed on the packaging.

Fentanyl, the active ingredient of the tablets, 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 Abstral?" below.

How to dispose of Abstral?

- Do not dispose of this medication through household waste. To prevent theft, diversion of the drug and misuse, the fentanyl sublingual tablets should always be stored in a suitable safe place.

Any unused or expired tablets should be returned to your pharmacist where they will be disposed of in accordance with national and local requirements.

Chapter 5: Dose Monitoring Card

- This dose monitoring card serves to keep a record of how many doses of the tablets 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 the tablet, make sure you or your carer fill it in the card with the date and time the medicine 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 use of these tablets. 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 use.

Sample (Can be modified)

Abstral

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

Doses Monitoring Card: Below is an example of the first three doses taken during initial titration.

Dose (Date and Time)	Amount of tablets taken
21.04.2023, 10:00 am	1
21.04.2023, 10:15 am	1
21.04.2023, 4:00 pm	1

Your contacts:

REPORTING A SUSPECTED SIDE EFFECT

You can report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

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

Side effects can also be reported to drugsafety.IE@grunenthal.com.

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

Doctor's name + phone number

Hospital or Practice

Pharmacy's name /phone
number

Emergency telephone

Other

This Brochure for Patients and Carers can also be requested from
IMedicalinformation@grunenthal.com

The patient information leaflet as contained in the package can be requested from
IMedicalinformation@grunenthal.com and/or downloaded from www.hpra.ie

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