

# Patient/carer's guide to PecFent (fentanyl citrate) nasal spray

## INTRODUCTION

Dear Patient/ Carer,

This brochure will provide you with information on how to properly use PecFent. 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 [drugsafety.UK@grunenthal.com](mailto:drugsafety.UK@grunenthal.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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## Chapter 1: Cancer and Pain

### What is PecFent and what is it used for:

PecFent 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. PecFent is a nasal spray (administered through the nose).

### 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 this pain suddenly becomes severe and much worse than the background pain, and can prevent one from carrying out 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 one experiences is not breakthrough pain.

### What to do if I have breakthrough pain?

People with breakthrough pain often need fast-acting strong painkillers such as PecFent® 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 2: Benefits and Risks**

### **Why is it important to follow the advice of your physician about PECFENT?**

PecFent is a very powerful medications 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 PecFent, especially if you are already on a medication that contains fentanyl (e.g. fentanyl patch).

### **What are some potential side effects of PecFent?**

Potential adverse effects can be seen in the patient's 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 PecFent 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 PecFent. PecFent overdose may cause dizziness, breathing difficulties, and may cause the heart to stop leading to death.

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

Abuse: the intentional and non-therapeutic use of PecFent 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 PecFent. It is important to note that the effect of Naloxone is short and one might still be in danger after administering naloxone. Therefore call an ambulance for immediate medical assistance if necessary.

### **How to avoid problems of misuse, abuse, dependence or addiction when using PecFent?**

Some people may be at a higher risk of experiencing problems when using PecFent. 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 PecFent appropriately.

### **The best way to prevent the risk of misuse or abuse of PecFent?**

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

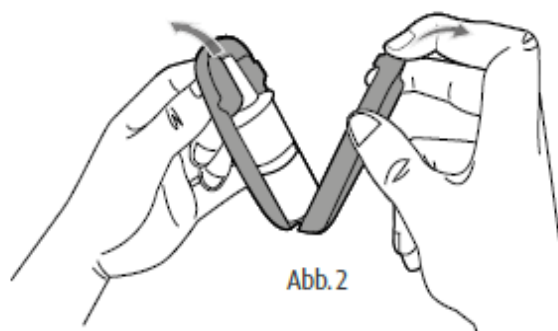
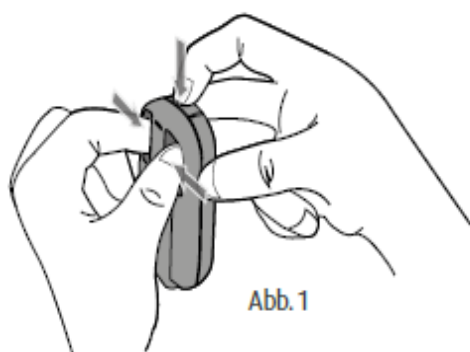
- First, remember that your doctor is there to help you relieve your pain and address your concerns about your medications. Your doctor will not judge you. Even small concerns need to be addressed.
- Talk with your doctor about how all your medications can work together to better manage your pain.
-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

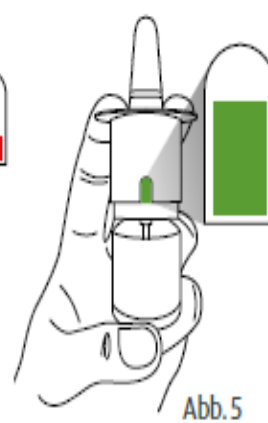
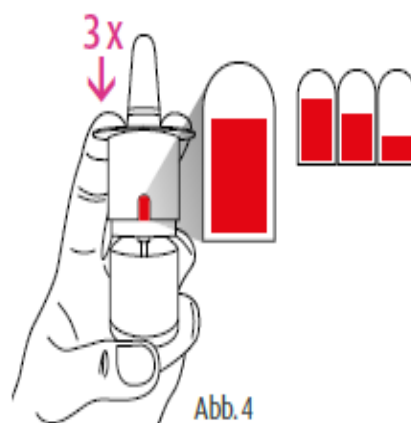
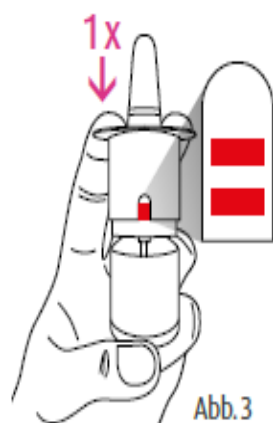
### Administration of PecFent

#### Opening and closing of the child safety container



1. To open the child-resistant container, insert fingers into rear cavities and squeeze while pushing down top button.
2. To close, push the two sides of the container against each other until you hear a click sound.

#### Preparation of the PecFent nasal spray bottle for use



Each new PecFent nasal spray bottle must be activated or prepared for initial use in the following way:

1. When unused, the spray bottle shows two red bars in the number window.
2. Press the grip recesses of the bottle firmly downward once, a "click" can be heard (Abb. 3). The display in the number window changes to a red bar.
3. The spray bottle must now be pressed three more times (Abb. 4). The display in the number window changes with each press.

4. When a green bar appears, the PecFent nasal spray bottle is ready for use (Abb. 5).

If the bottle has not been used for more than 5 days, the bottle must be prepared before further use by triggering a spray. During preparation, the sprays must not be directed at yourself, other people, surfaces, or objects that may come into contact with other people, especially children.

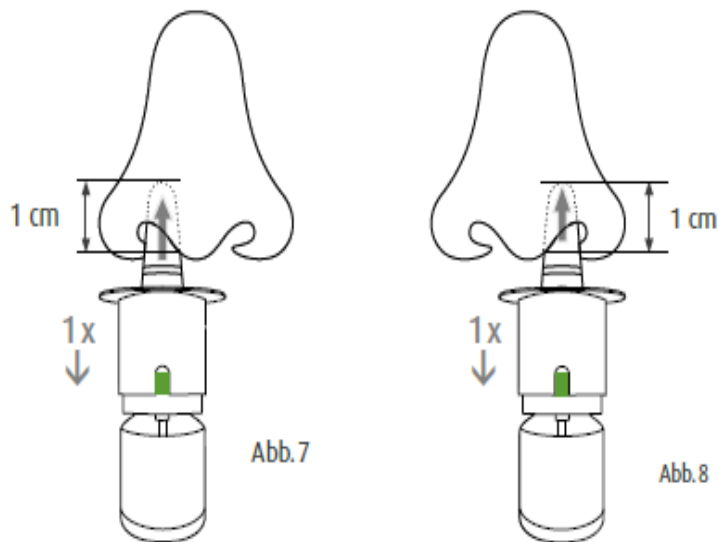
The spray bottle is equipped with an automatic counter and always contains 8 sprays (or 2 sprays for 2 spray bottles). The counting begins after the bottle has been activated during the first use and indicates how many sprays have already been used (Abb. 6).

After the bottle has been prepared, it should not be used for more than 60 days



Abb. 6

#### Correct usage of PecFent® nasal spray



1. Remove the protective cap.
2. Insert the tip of the spray approximately 1 cm into one nostril (Abb. 7).
3. To trigger a spray, firmly press the grip recesses of the bottle downward until a click is heard and the number in the number window increases by 1.
4. Depending on the prescribed dosage, an additional spray may need to be administered into the other nostril (Abb. 8).
5. Do not blow your nose immediately after application to ensure that the entire active ingredient remains in the nose.
6. After use, replace the protective cap and place the spray bottle back into the child-resistant container.

## Dosage and Titration

PecFent is available in two strengths

- Yellow pack- 100 mcg/ spray strength
- Violet pack- 400 mcg/ spray strength



Yellow carton  
100 microgram/spray  
strength



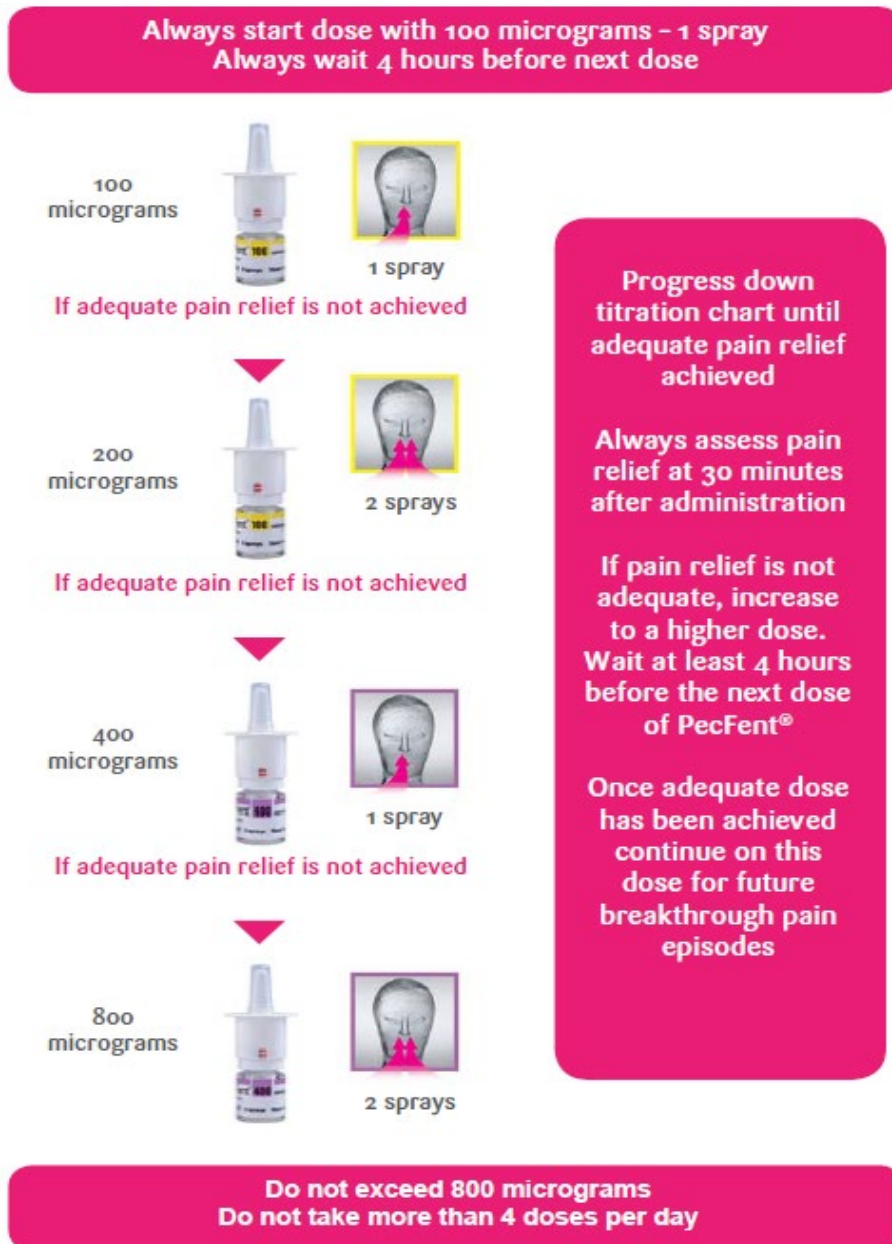
Violet carton  
400 microgram/spray  
strength

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## Initial dose

- Before taking PecFent for the first time, your doctor will explain how PecFent should be taken to effectively treat your breakthrough pain.
- The first dose should be initiated on a dose of 100 mcg (one spray) and then titrated to an “effective dose” using the titration scheme outlined below.
- The initial dosing applies even for patients switching from other fentanyl-containing products for their cancer breakthrough pain (CBTP).
- Your doctor will monitor you closely whilst finding the best dose for you, to find the optimal dose and to minimize the risk of adverse reactions.

## Titration



Patients whose initial dose is 100 mcg (one spray) and who need to titrate to a higher dose due to lack of effect can be instructed to use two 100 mcg sprays (one in each nostril) for their next CBTP episode.

If the dose is not successful, you may be prescribed a bottle of PecFent 400 mcg spray and instructed to change to one 400 mcg spray for your next pain episode. If the dose is still not successful, you may be instructed to increase to two 400 mcg sprays (one in each nostril).

Do not exceed 800 mcg or take more than 4 doses per day.

From treatment initiation, you should be closely monitored and the dose titrated until an effective dose is reached and confirmed for two consecutive treated episodes of CBTP. A review of the background opioid therapy may be required if patients consistently present with more than four breakthrough cancer pain episodes per 24-hours.



### Discontinuation

Your pain will be monitored and re-evaluated when renewing prescriptions or during your doctor's visits. PecFent 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 the treatment with PecFent.

## **Chapter 4: Storage/Safety Information and Disposal of PecFent**

### **How to store PecFent?**

PecFent Nasal Spray can cause life-threatening breathing difficulties if ingested by individuals, especially children, for whom it was not prescribed. Additionally, there is a risk of the medication being stolen by individuals who misuse prescription medications.

Therefore, after each use, immediately place PecFent Nasal Spray back into the child-resistant container and store it at all times in a secure location inaccessible to unauthorised individuals and children. This also applies to empty spray bottles.

To prevent theft, diversion of the drug and misuse, PecFent should always be stored in a suitable safe place. Fentanyl, the active ingredient of PecFent 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 PecFent?".

### **How to dispose of PecFent?**

Medication residues in empty or no longer needed spray bottles can have life-threatening consequences if used by other individuals.

- If not all sprays of a bottle have been used, the bottle must be emptied before disposal. To do this, hold the bottle away from yourself and others, and trigger sprays until the red number "8" (or "2" for 2 spray bottles only) appears in the number window.
- For empty spray bottles, number window shows "8" (or "2" for 2 spray bottles only), the spray device must then be activated a total of four more times. You will feel greater resistance, no clicking sound will be heard, and the number display will remain at "8" (or at "2" for 2 spray bottles only).
- The empty bottle must be stored in the child-resistant container and taken to a pharmacy for disposal.
- Do not dispose of unused or expired bottles through sewage or household waste. They should be returned to the pharmacy for proper disposal.

**Chapter 5: Dose Monitoring Card**

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

**Sample (Can be modified)**

**PecFent**

**100/400 micrograms(mcg) nasal spray**

Doses Monitoring Card: First 3 lines are examples

Dose (Date and Time)	Amount of spray 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 SIDE EFFECTS**

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](http://www.mhra.gov.uk/yellowcard)
- the free Yellow Card app available from the Apple App Store or Google Play Store.

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 [drugsafety.UK@grunenthal.com](mailto:drugsafety.UK@grunenthal.com).

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

Doctor's name + phone number

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Hospital or Practice

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Pharmacy's name /phone number

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Emergency telephone

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Other 

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This PecFent brochure for patients and carers can be requested from [ukmedicalinformation@grunenthal.com](mailto:ukmedicalinformation@grunenthal.com) and/or downloaded from <https://www.medicines.org.uk/emc/rmm/2892/Document>

The PecFent patient information leaflet as contained in the package can be requested from [ukmedicalinformation@grunenthal.com](mailto:ukmedicalinformation@grunenthal.com) and/or downloaded from <https://www.medicines.org.uk/emc/files/pil.9484.pdf>