

Patient Brochure

How to use PecFent[®]

This information should be read
in conjunction with the
Patient Information Leaflet
contained in the PecFent carton



PecFent

FENTANYL NASAL SPRAY



Introduction

The purpose of this booklet is to provide you and your carers with useful information about breakthrough cancer pain and treatment with PecFent (fentanyl nasal spray) including:

1. What is breakthrough cancer pain?
2. What PecFent is and what it is used for
3. What you need to know about PecFent
4. Starting treatment with PecFent
5. How to use PecFent
6. How to store PecFent safely
7. When to contact your doctor
8. Summary
9. Who to ask for further information

This document summarises important information from the PecFent Patient Information Leaflet (contained in the carton), but is not intended to replace it.

What is breakthrough cancer pain?

Constant background pain is one of the most common symptoms of cancer. Your doctor will have given you medicine to treat this constant pain. Despite taking this medicine you may experience sudden, severe and intense episodes of pain. As this pain “breaks through” the control given by your regular medicine it is called breakthrough cancer pain.

Breakthrough cancer pain:

- “Breaks through” the control of your ongoing pain medicine
- Generally lasts 30-45 minutes
- Is severe and intense
- Is rapid in onset
- Is often unpredictable (but can be triggered by things such as walking or coughing)

As breakthrough cancer pain is separate from constant background pain there are specific medicines to treat it. Your doctor has prescribed a form of breakthrough cancer pain medicine called PecFent and this booklet is designed to help you use this medicine.

What PecFent is and what it is used for

- PecFent is a pain-relieving medicine containing a strong pain killer called fentanyl and has been specifically designed to relieve breakthrough cancer pain
- PecFent is a nasal spray
- When you spray PecFent into your nose the very small spray droplets form a thin gel on the lining of your nose
- This gel is usually not noticeable to you, and will disappear from your nose (through swallowing) within 30 minutes
- Fentanyl is absorbed quickly from the gel droplets through the lining of your nose into the blood stream
- Your doctor has prescribed PecFent for the relief of breakthrough cancer pain that you might be experiencing, despite taking other pain killers on a daily basis
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours

As with similar pain medicines, PecFent can cause serious side-effects and carries a risk of accidental overdosing and a risk of addiction. You should use PecFent only if you have received information regarding the safe use of the device and other precautions from your doctor and/or pharmacist. It is important that you read and understand the information in this brochure and the Patient Information Leaflet provided with your medicine. Please ask your doctor or your pharmacist if you have any questions or need additional information.

- **Do not** use PecFent to treat any other short-term pain such as headaches or back pain
- **Do not** use PecFent to treat more than 4 episodes of breakthrough cancer pain a day
- **Leave at least 4 hours** between each dose of PecFent
- **Do not** change the dose of PecFent unless your doctor tells you to

Fentanyl overdose can be life-threatening

- Make yourself and your family/carer aware of the signs of fentanyl overdose and what to do if you experience them
- Symptoms of fentanyl overdose include:
 - Extreme drowsiness
 - Infrequent breathing or shallow breathing
 - Problems walking, talking and thinking compared to normal
 - Convulsions (fits or seizures)
- Steps to take if fentanyl overdose is suspected:
 - Stay calm
 - Try to keep the patient awake by calling their name and talking to them, pinching their earlobe or rubbing your knuckles on their breastbone
 - Call an ambulance (dial 999)
 - Keep the PecFent bottle/Patient Information Leaflet to show the emergency team

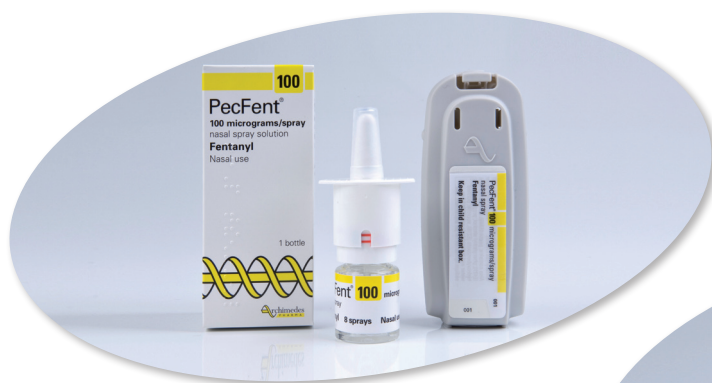
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Starting treatment with PecFent

Breakthrough cancer pain is a very individual experience and differs from person to person. Therefore, it is important that you work closely with your doctor to find the right dose of PecFent to relieve your breakthrough cancer pain (the process of finding the right dose is called “titration”).

PecFent bottle and packaging

PecFent is available in two strengths. The cartons, child-resistant containers and bottles are colour-coded so you can tell them apart.



Yellow carton
100 microgram/spray strength



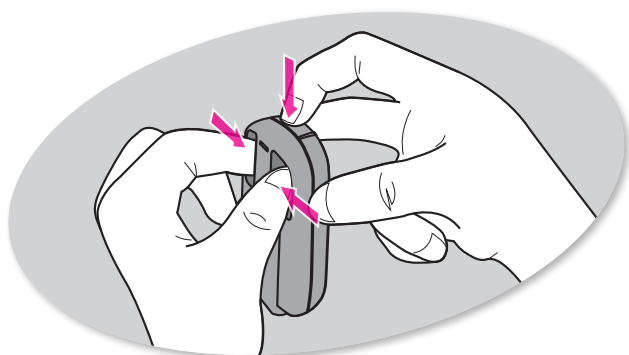
Violet carton
400 microgram/spray strength

PecFent is contained in a clear glass bottle, fitted with a pump which delivers an exact dose of medicine with each spray. The pump has a spray counter that clicks so you can hear as well as see that the spray has been given (this is important because the spray is very fine and you may not feel it – you should rely on the click and counter to check you have correctly administered a spray).

- The click provides an audible signal that the spray has been administered
- The number on the counter moves forward providing a visual signal of how many sprays have been used

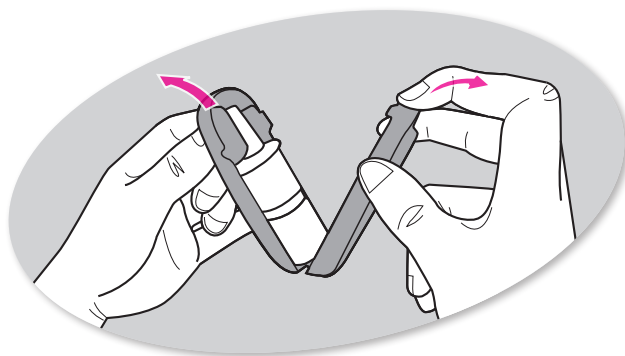
The PecFent bottle also has an end-of-use lock and a protective cap. After the PecFent bottle has been primed (prepared for use), it delivers 8 sprays. The nasal spray pump locks after the eighth spray has been used. The PecFent bottle must always be stored in the child-resistant container.

Instructions on how to open and close the child-resistant container



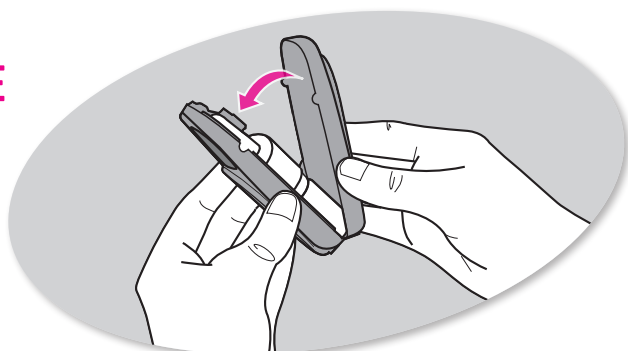
1. Insert fingers into rear cavities and squeeze while pushing down top button

OPEN



2. Open

CLOSE



3. Close (listen for confirmation click)

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Finding your dose

PecFent can deliver 100, 200, 400 and 800 microgram doses as follows:

Pack colour	Dose required (microgram)	Product strength (microgram/spray)	Amount
Yellow	100	100	One spray administered into one nostril
Yellow	200	100	One spray administered into both nostrils
Violet	400	400	One spray administered into one nostril
Violet	800	400	One spray administered into both nostrils

The starting dose of PecFent is always 100 micrograms (even if your doctor is switching you from another fentanyl product). If this dose does not relieve your breakthrough cancer pain, your doctor will increase the dose. You may need to try a number of doses over the course of a few breakthrough cancer pain episodes to find the most effective one to relieve your pain. During the titration period you should:

- Keep a record of your pain
- Update your doctor
- Follow your doctor's instructions

PecFent is only to be used by spraying into your nostril

Preparing (priming) the PecFent bottle for use

Before you use a new bottle of PecFent you need to prepare it for use. This is called 'priming'.

To prime the bottle, please follow the instructions below:

1. A new bottle of PecFent will show two red lines in the counting window in the white plastic top on the bottle (Figure 1 and Figure 3a)
2. Take off the clear plastic protective cap from the nozzle (Figure 1)

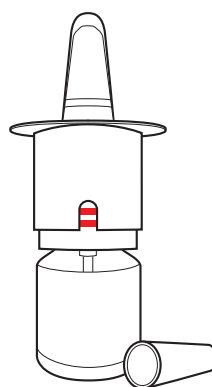


Figure 1

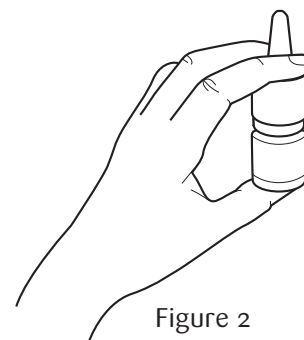


Figure 2



Figure 3

3. Aim the nasal spray away from you (and any other people or animals)
4. Hold the PecFent nasal spray upright with your thumb on the bottom of the bottle, and your first and middle fingers on the finger grips each side of the nozzle (Figure 2)
5. Firmly press down on the finger grips until a 'click' is heard and then let go of the grips (Figure 2). You will hear a second 'click' and there should now be a single large red bar in the counting window (Figure 3b)

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- Repeat step 5 three times. As you repeat step 5, the red bar will become smaller and smaller until you see a green bar in the counting window (Figure 3b-e). The green bar means the PecFent nasal spray is ready to use
- Wipe the nozzle with a tissue and flush the tissue down the toilet
- If you are not going to take your medicine straight away, put the protective cap back on. Then put the PecFent bottle in the child-resistant storage container. Once you have primed the PecFent bottle you must start using it within 5 days
- Write the date that you primed the PecFent bottle in the space on the child-resistant container label



Figure 3

Using PecFent for the first time

- Check that there is green bar showing in the counting window (Figure 4), this confirms that PecFent bottle has been primed (see 'Preparing the PecFent bottle for use' above)
- Blow your nose if you feel you need to
- Sit down with your head upright
- Take off the protective cap from the nozzle
- Hold the PecFent bottle with your thumb on the bottom of the bottle and your first and middle fingers on the finger grips (Figure 4)

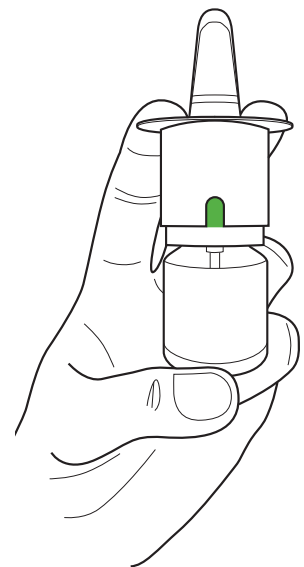


Figure 4



Figure 5

- 6.** Put the nozzle a short distance (about 1 cm) into your nostril. Point it slightly inwards towards the middle wall of your nose. This will tilt the bottle slightly (Figure 5)
- 7.** Close the other nostril with a finger from your other hand (Figure 5)

- 8.** Firmly press down on the finger grips so that PecFent sprays into your nostril. When you hear a click let go of the grips. Note: You may not feel anything happen in your nose at all – do not trust this to mean the spray did not operate – rely on the click and number counter. The counting window will now show a black “1” confirming the spray has been delivered
- 9.** Breathe in gently through your nose and out through your mouth
- 10.** If your doctor has prescribed a second spray, repeat steps 5 to 9, using the other nostril. Do not use more than the dose that your doctor prescribes to treat any single pain episode. If you have used a second spray, the counting window will now show a black “2” confirming the spray has been delivered
- 11.** Put the bottle back in the child-resistant container after each use. Keep out of the reach and sight of children (Figure 6)

Do not use more than the dose that your doctor prescribes to treat any single pain episode

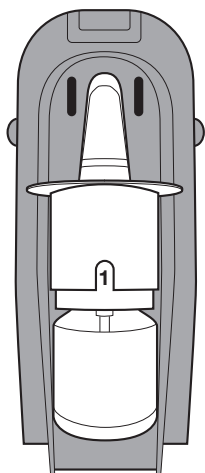


Figure 6

- 12.** Stay sitting for at least 1 minute after using the nasal spray
- 13.** Do not blow your nose straight after using the PecFent nasal spray

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Using a PecFent bottle you have used before

- 1.** Check the bottle is within its use-by (expiry) date. Dispose of the bottle (see Section 6 How to store PecFent safely) and prime a new one if:
 - More than 14 days have passed since the bottle was primed (to help you remember, there is a space on the child-resistant container label for you to write the date of first use)
 - if it has been more than 5 days since the bottle was last used
- 2.** Make sure there is a black number in the counting window then follow sections 2-13 Using PecFent for the first time
- 3.** If there is a red “8” in the counting window, the bottle is empty and should be disposed of safely and you should prime a new bottle



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How to store PecFent safely

PecFent could be life-threatening if taken by a child by accident. Therefore it is very important that you always follow these storage instructions:

- Keep the PecFent bottle in the child-resistant container and store out of the sight and reach of children
- Put the PecFent bottle in the child-resistant container immediately after each use
- Empty PecFent bottles should still be stored in the child-resistant container

In addition:

- **Do not** use PecFent after the expiry date stated on the carton and bottle. PecFent that has passed its expiry date, or is no longer required, may still contain enough medicine to be harmful. Any used or unused bottles should be returned to the pharmacy or disposed of according to local requirements
- Your pharmacist or doctor will be able to tell you how to dispose of used or unused bottles of PecFent safely
- Because PecFent contains a medicine that is attractive to people who abuse drugs such as narcotics, store it in a secure location



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When to contact your doctor

- You should contact your doctor if you have any questions or concerns about how to use PecFent, or what dose to take
- If PecFent does not seem to be effective you should contact your doctor
- If you need to use more than the maximum allowed 4 doses of PecFent a day you should contact your doctor as this may be an indication that your regular daily medication should be changed
- If the PecFent seems to be causing side-effects you should contact your doctor
- If you develop symptoms of fentanyl overdose you should seek medical assistance immediately (see section 3 What you need to know about PecFent)

- Breakthrough cancer pain is different to background cancer pain
- PecFent is a fentanyl nasal spray developed specifically to treat breakthrough cancer pain
- PecFent should only be used to treat breakthrough cancer pain
- PecFent must only be used by patients taking strong pain killers (opioids) to treat their constant background pain
- PecFent must always be stored in the child-resistant container
- When PecFent is no longer needed, used and unused bottles should be returned to the pharmacy or disposed of in accordance with local requirements
- You may not feel anything happen in your nose when you use PecFent, therefore always rely on the click and counter
- Contact your doctor if you have any questions about using PecFent

If you have any further questions on PecFent, please ask your nurse, doctor or pharmacist

Doctor's name

Hospital/surgery/hospice

Nurse's name

Hospital/surgery/hospice

Emergency telephone number

Hospital/surgery/hospice stamp

You can contact the Archimedes Pharma Medical Information department on:
0118 9315094

Educational material provided by:

Archimedes Pharma UK Limited, 250 South Oak Way, Green Park, Reading, Berkshire RG2 6UG

Telephone: +44 (0)118 931 5094

Further information on PecFent is also available on the PecFent website at www.PecFent.com