

Package leaflet: Information for the user

PecFent 100 micrograms/spray nasal spray, solution **PecFent 400 micrograms/spray nasal spray, solution** Fentanyl

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PecFent is and what it is used for
2. What you need to know before you use PecFent
3. How to use PecFent
4. Possible side effects
5. How to store PecFent
6. Contents of the pack and other information

1. What PecFent is and what it is used for

What PecFent is

PecFent contains fentanyl, which is a strong pain-relieving medicine known as an opioid pain killer.

What PecFent is used for

PecFent is used in adults with cancer for a type of pain called 'breakthrough' pain.

- Breakthrough pain comes on suddenly.
- It comes on even though you have taken your usual opioid pain killer (such as morphine, fentanyl, oxycodone or hydromorphone) to control your constant background pain.

PecFent is only to be used by adults who are already taking other opioid medicines daily for their constant cancer pain.

How PecFent works

PecFent is a nasal spray, solution

- When you spray PecFent into your nose the very small spray droplets form a thin gel.
- Fentanyl is absorbed quickly through the lining of your nose and into the blood stream.
- This means the medicine gets into your system quickly to relieve your breakthrough pain.

2. What you need to know before you use PecFent

Do not use PecFent if:

- you are allergic to fentanyl or any of the other ingredients of this medicine (listed in Section 6).
- you are not regularly using a prescribed opioid medicine (e.g codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine), every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you **must not** use PecFent, because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop.
- you suffer from short-term pain other than breakthrough pain.
- you have a serious breathing or lung problem.

Do not use PecFent if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using PecFent.

Warnings and precautions

Keeping PecFent safe from children

- You must keep PecFent in the child resistant storage container when you are not using it, even if you have used all 8 sprays. This is because PecFent could be life-threatening if taken by a child by accident.

Check with your doctor or pharmacist before using PecFent if:

- you have not been taking the same dose of your daily opioid medicine for your constant pain for some time
- you have breathing problems such as asthma, wheezing or shortness of breath
- you suffer a severe blow to the head
- you have problems with your heart especially slow heart rate
- you have low blood pressure or a low amount of fluid in your circulation
- you have liver or kidney problems. This is because it may affect the way in which your body breaks down the medicine.
- you take antidepressants or antipsychotics, please refer to the section '**Other medicines and PecFent**'.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using PecFent.

- If you are an athlete, using PecFent may result in positive doping-tests.

Consult your doctor while using PecFent if:

- you suffer from recurrent nose bleeding - he may advise an alternative treatment
- you feel that PecFent is becoming less effective in treating your episodes of breakthrough pain
- 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
- you think you are becoming dependent on PecFent
- you experience a combination of the following symptoms: nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Together these symptoms may be a sign of a potentially life-threatening condition called adrenal insufficiency, a condition in which the adrenal glands do not produce enough hormones
- you have ever developed adrenal insufficiency or lack of sex hormones (androgen deficiency) with opioid use.

Children and adolescents

PecFent is not approved for use in children under 18 years of age.

Other medicines and PecFent

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular tell your doctor or pharmacist before using PecFent if you are taking or have recently taken any of the following medicines:

- medicines that might make you sleepy such as sleeping tablets, tranquilisers, muscle relaxants, medicines for anxiety or medicines for allergies (anti-histamines)
- medicines for depression called 'monoamine-oxidase inhibitors' (MAOI). Tell your doctor or pharmacist if you have taken an MAOI medicine in the past 2 weeks before using PecFent. The risk of side effects increases if you are taking medicines such as certain antidepressants or antipsychotics. PecFent may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature

above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Your doctor will tell you whether PecFent is suitable for you.

- nasal sprays to treat a stuffy nose (containing a decongestant such as oxymetazoline)
- medicines that might have an effect on the way your body breaks down PecFent. These include:
 - medicines for HIV infection (such as ritonavir, nelfinavir, amprenavir or fosamprenavir)
 - medicines for fungal infections (such as ketoconazole, itraconazole or fluconazole)
 - medicines for bacterial infections (such as troleandomycin, clarithromycin or erythromycin)
 - ‘aprepitant’ - used to stop you feeling sick
 - ‘diltiazem’ and ‘verapamil’ - used for high blood pressure or heart problems.
 - other pain killers called partial agonist/antagonist like buprenorphine, nalbuphine, pentazocine. You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines.

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before using PecFent.

Don't use any other kind of nasal spray for at least 15 minutes after using PecFent.

PecFent with food, drink and alcohol

- Do not drink alcohol while using PecFent. It can increase the risk of getting serious side effects.
- Do not drink grapefruit juice while using PecFent. It may affect the way your body breaks down PecFent.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Do not use PecFent if you are pregnant or might get pregnant, unless your doctor has told you to.
- Do not use PecFent during child birth. This is because it may cause breathing problems in your baby.
- Do not use PecFent if you are breast-feeding. This is because the medicine can get into your breast milk and may cause side effects in the breast-fed child.
- You should not start breast-feeding within 5 days after the last dose of PecFent.

Driving and using machines

- Talk to your doctor about whether it will be safe for you to drive or use tools or machines after using PecFent.
- You may feel sleepy, dizzy or have problems with your eyesight after using PecFent. If this happens, do not drive or use any tools or machines.
- Do not drive or use tools or machines until you know how this medicine makes you feel.

PecFent contains propylparahydroxybenzoate (E216).

May cause allergic reactions (possibly delayed), and exceptionally, bronchospasm (if you do not use the nasal spray correctly).

3. How to use PecFent

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PecFent comes in two different strengths: a 100 microgram per spray bottle and a 400 microgram per spray bottle. Make sure that you use the strength that your doctor has prescribed for you.

How much to use

- A dose to treat a breakthrough pain episode might be either 1 spray or 2 sprays (one in each nostril). Your doctor will tell you how many sprays (1 or 2) you should use to treat your breakthrough pain episode.
- **Do not use more than the dose your doctor prescribes for any single breakthrough pain episode.**
- Do not use PecFent more than 4 times daily
- Wait at least 4 hours to take the next dose of PecFent.

Starting dose

- The starting dose is 100 micrograms.
- This is a single spray into one nostril from the 100 microgram per spray bottle.
- See 'Using the PecFent bottle' for instructions on how to use a dose.

Finding the right dose

- Your doctor will then help you find the right dose to relieve your breakthrough pain. It is very important to follow your doctor's instructions.
- Tell your doctor about your pain and how PecFent is working. Your doctor will decide if your PecFent dose needs to be changed.
- Do not change the dose yourself.

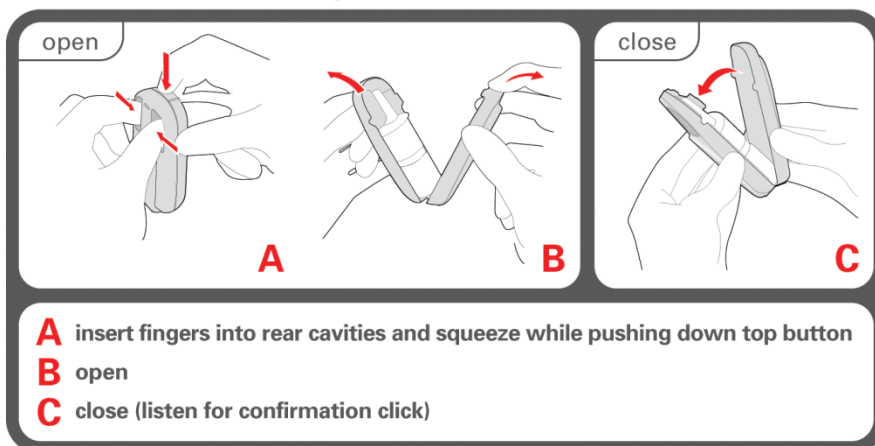
Once you have found the right dose

- Tell your doctor if your dose of PecFent does not relieve your breakthrough pain. Your doctor will decide if your dose needs to be changed. **Do not change the dose of PecFent or your other pain medicines yourself.**
- Tell your doctor straight away if you have more than 4 episodes of breakthrough pain a day. Your doctor may change the medicine for your constant pain. Once your constant pain is controlled, your doctor may then change your dose of PecFent.

If you are not sure about the right dose or how much PecFent to use, ask your doctor.

Using the PecFent bottle

Instructions on how to open and close the child resistant container



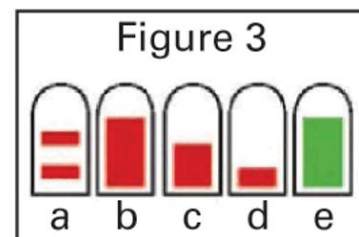
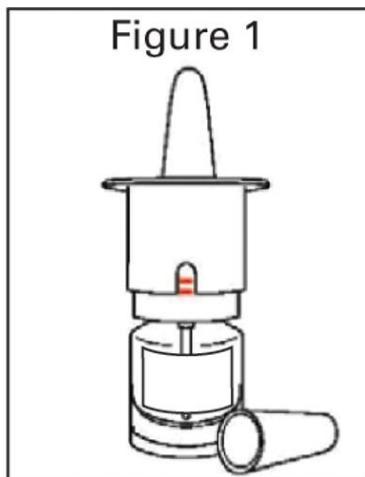
Preparing the PecFent bottle for use

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).
3. Aim the nasal spray away from you (and any other people).
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).
6. 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.
7. Wipe the nozzle with a tissue and flush the tissue down the toilet.
8. If you are not going to use your medicine straight away, put the protective cap back on. Then put the PecFent bottle in the child-resistant storage container. If PecFent has not been used for 5 days, re-prime by spraying once.



Using PecFent

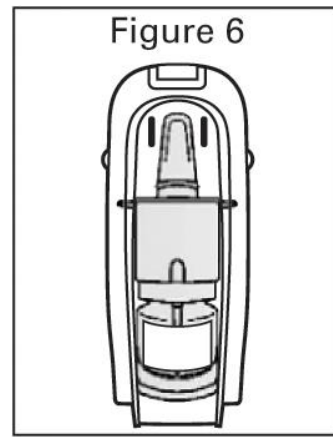
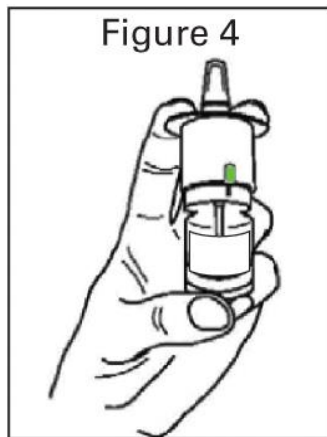
PecFent is only to be used by spraying into your nostril.

1. Check that there is a green bar or a number showing in the counting window (Figure 4): this confirms that the PecFent bottle has been primed (see ‘Preparing the PecFent bottle for use’ above).
2. Blow your nose if you feel you need to.
3. Sit down with your head upright.
4. Take off the protective cap from the nozzle.
5. 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).
6. Put the nozzle a short distance (about 1 cm) into your nostril. Point it inwards towards the 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.
9. Breathe in gently through your nose and out through your mouth.
10. The number counter will move forward after each use and show how many sprays have been used.
11. 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.

12. Put the bottle back in the child-resistant container after each use. Keep out of the sight and reach of children (Figure 6)

13. Stay sitting for at least 1 minute after using the nasal spray.



Number of sprays in a PecFent bottle

There are 8 full sprays in each PecFent bottle.

- After the first spray, number 1 will appear in the counting window. This will go up each time the spray is used.
- When you see a red 8 in the counting window, the bottle is finished and you will no longer be able to get a full spray from it.

Disposal of unused PecFent

If you can see a number, other than 8 in the counting window, you have **NOT** used all 8 sprays in the bottle. There are still doses of PecFent left in the bottle.

You must empty the remaining doses of PecFent from the bottle by aiming the nasal spray away from you (and any other people) and pressing and releasing the grips until the red number “8” appears in the counting window.

When you see the number “8” in the counting window, there is still medicine in the bottle that you must empty.

- You will need to press down and release the finger grips 4 more times while aiming the nasal spray away from you (and any other people).
- You will feel some increased resistance when you press down and the finger grips will only move a small amount.
- You will **NOT** hear a click when you press down .
- The counter will stay on the number “8”.
- Put the protective cap back on the spray bottle.
- Put the bottle back in the child resistant container.
- Speak to your local pharmacy about disposal of empty bottles (see ‘**How to store PecFent**’)

If the PecFent nasal spray is blocked or does not spray properly

- If the spray is blocked, aim the spray away from you (and any other people) and push firmly down on the pump. This should clear any blockage.
- If your nasal spray is still not working properly, dispose of the faulty bottle and start a new one. Tell your doctor what happened. **Never try to fix the nasal spray yourself or take it apart.** This is because it may then give you the wrong dose.

Dispose of the PecFent bottle and start a new one if:

It has been 60 days or more since you primed or used your bottle for the first time.

If you use more PecFent than you should

- If you use more PecFent than you should, you may feel sleepy, sick, dizzy or have slow or shallow breathing. In severe cases taking too much PecFent may also lead to coma. If you feel

very dizzy, very sleepy or have slow or shallow breathing, call an ambulance or ask someone else to call one straight away.

If you stop using PecFent

If you no longer have breakthrough pain, talk to your doctor before stopping PecFent and follow his/her advice. However, you should keep taking your other opioid medicine to treat your constant pain. Your doctor may need to check the dose.

You may experience withdrawal symptoms similar to the possible side effects of PecFent when discontinuing PecFent. If you experience withdrawal symptoms, you should contact your doctor. Your doctor will evaluate if you need medicine to reduce or eliminate the withdrawal symptoms.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Call an ambulance or ask someone else to call one straight away if you:

- feel very dizzy or faint
- feel very sleepy
- get slow or shallow breathing
- get cold clammy skin, look pale, have a weak pulse or other signs of shock.

If you or your carer notice any of the side effects above, call an ambulance straight away.

Common side effects (may affect up to 1 in 10 people):

- not knowing where you are (disorientated)
- change in taste
- feeling dizzy
- feeling or being sick
- feeling sleepy, headache
- nose bleed, discomfort in the nose, runny nose
- constipation
- itchy skin

Uncommon side effects: (may affect up to 1 in 100 people):

- chest infection
- painful, sore or inflamed throat or nose
- cough, sneezing, catarrh or cold, changes in the fluid produced by your nose
- allergic reaction, rash
- loss of or increase in appetite, weight increase
- dehydration, feeling thirsty
- misusing the medicine
- seeing or hearing things that are not really there (hallucinations/delirium), feeling confused
- feeling depressed, worried, slow or nervous
- a lack of concentration or increased activity
- memory loss
- feeling “high”
- being less aware or responsive, losing consciousness
- convulsion (fits)
- muscle convulsions or trembling
- loss of taste, loss or change in sense of smell
- difficulty in speaking

- blue skin colour
- vertigo, falling over, malaise
- heat and circulation not working properly, hot flush or fever, chills, excessive sweating
- swelling of the soft tissue
- low blood pressure
- blockage in the wind-pipe
- shortness of breath
- vaginal bleeding
- tear in the intestine or inflammation of the stomach lining
- numbness or tingling in the mouth, tongue, or nose, or other tongue problems, mouth ulcers, dry mouth
- diarrhoea
- retching, stomach pains, indigestion
- sore or painful joints
- difficulty in or inability to pass water
- chest pain
- feeling tired or weak, problems moving
- changes in blood cells (detected by laboratory tests)
- increased blood sugar
- protein in the urine

Other side effects (frequency not known (frequency cannot be estimated from the available data))

- Severe breathing problems
- Flushing
- Insomnia
- Withdrawal syndrome (may manifest by the occurrence of the following side effects nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating)
- Drug dependence (addiction)
- Drug abuse

Prolonged treatment with fentanyl during pregnancy may cause withdrawal symptoms in the newborn which can be life-threatening (see section 2).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store PecFent

Keep this medicine out of the sight and reach of children. PecFent could be life-threatening if taken by a child by accident.

- Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.
- Do not store PecFent above 25°C.
- Do not freeze.
- Keep the bottle in its child resistant container in order to protect from light.
- Store the PecFent bottle in the child resistant container at all times, even when finished.
- Do not use for more than 60 days after first use (either priming or using to treat a breakthrough pain episode).

- PecFent that has passed the expiry date or is no longer required may still contain enough medicine to be harmful to other people, especially children. PecFent should not be disposed of via wastewater or household waste. Any unwanted PecFent should be disposed of as soon as possible following the instructions under ***Disposal of unused PecFent***. Any empty bottles should be returned to their child resistant container and discarded by taking them back to the pharmacy or according to local requirements.

6. Contents of the pack and other information

What PecFent contains

The active substance is fentanyl.

- *PecFent 100 micrograms/spray nasal spray, solution*
Each ml of solution contains 1,000 micrograms fentanyl (as citrate).
1 spray (100 microlitres) contains 100 micrograms fentanyl (as citrate).
- *PecFent 400 micrograms/spray nasal spray, solution*
Each ml of solution contains 4,000 micrograms fentanyl (as citrate).
1 spray (100 microlitres) contains 400 micrograms fentanyl (as citrate).

The other ingredients (excipients) are pectin (E440), mannitol (E421), phenylethyl alcohol, propylparahydroxybenzoate (E216), sucrose, purified water and hydrochloric acid or sodium hydroxide for pH adjustment.

What PecFent looks like and contents of the pack

The medicine is a clear to almost clear, colourless nasal spray, solution. It is contained in a clear glass bottle, fitted with a metering pump. The pump has a spray counter that clicks, so you can hear as well as see that the spray has been given and a protective cap. After the PecFent bottle has been primed (prepared for use) it delivers 8 full sprays. Each PecFent bottle is supplied in a child resistant container.

PecFent bottles in their child resistant containers are supplied in cartons containing 1, 4 or 12 bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu/>.