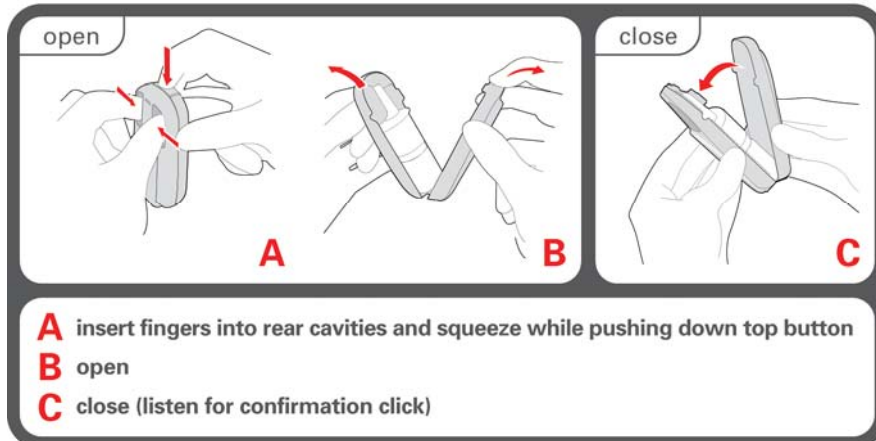


Instructions on how to open and close the child resistant container



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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What PecFent is and what it is used for
2. Before you use PecFent
3. How to use PecFent
4. Possible side effects
5. How to store PecFent
6. Further information

1. WHAT PECFENT IS AND WHAT IT IS USED FOR

What PecFent is

PecFent 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.

- 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. BEFORE YOU USE PECFENT

Do not use PecFent if:

- you are allergic (hypersensitive) to fentanyl or any of the other ingredients of PecFent (listed in Section 6).
- you are **not** regularly using a prescribed opioid medicine (e.g. codeine, fentanyl, hydromorphone, morphine, oxycodone, pethidine) for your constant 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.

Take special care with PecFent

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

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 heart problems such as a very 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.

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, taking PecFent may result in positive doping-tests.

Please also tell your doctor if after using PecFent:

- 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 think you are becoming dependent on PecFent

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines you get without a prescription, such as herbal 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
- 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 like buprenorphine, nalbuphine, pentazocine

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.

Using PecFent with food and drink

- 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 and breast-feeding

- 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, unless your doctor has told you to. This is because the medicine can get into your breast milk and may cause side effects in the breast-fed child.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Important information about some of the ingredients of PecFent

PecFent contains propylhydroxybenzoate (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 PecFent exactly as your doctor has told you. You should 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

- Do not use PecFent more than 4 times daily
- Wait at least 4 hours to take the next dose of PecFent.

- 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.**

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 take 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

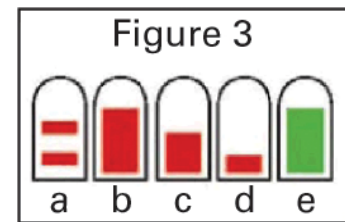
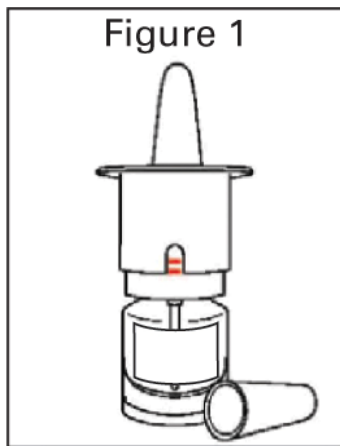
PecFent is only to be used by spraying into your nostril.

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 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).
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 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.



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

- it has been 14 days or more since you primed or used your bottle for the first time.
- it has been 5 days or more since you last used this bottle of PecFent.

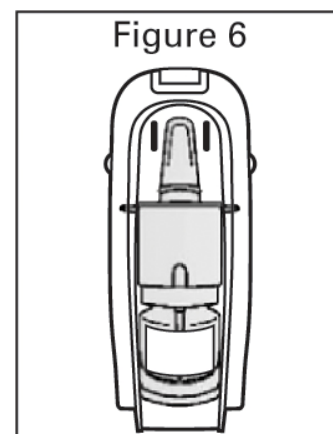
Dispose of the PecFent bottle and start a new one if either of the above apply to you.

Using PecFent

1. Check that there is 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 reach and sight 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 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, there are no more sprays left and the pump will lock. Put the bottle back in the child resistant container.

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 or animals) 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.

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. 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, PecFent can have 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.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 in every 10 users)

Common (affects 1 to 10 users in every 100 users)

Uncommon (affects 1 to 10 users in every 1,000 users)

Rare (affects 1 to 10 users in every 10,000 users)

Very rare (affects less than 1 user in every 10,000 users)

Not known (frequency cannot be estimated from the available data).

Common side effects:

- 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:

- 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
- abusing or misusing the medicine
- seeing or hearing things that are not really there (hallucinations/delirium), feeling confused
- depressed, worried, slow or nervous
- a lack of concentration or increased activity
- memory loss
- feeling “high”
- being less aware or responsive, losing consciousness
- muscle convulsions or trembling,
- loss of taste, loss or change in sense of smell
- difficulty in speaking
- blue skin colour
- vertigo, falling over
- 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 or tongue, 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)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PECFENT

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

- Do not use PecFent 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 use for more than 14 days after first use (either priming or using to treat a breakthrough pain episode).
- Write the date of first use in the space provided on the label of the child resistant container.

- If it is more than 5 days since you last used the PecFent nasal spray, dispose of the bottle, following the instructions below, and use a new bottle.
- Protect from light.
- 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.
- 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 used or unused bottles should be returned to their child resistant container and discarded as soon as possible by taking them back to the pharmacy or according to local requirements.

6. FURTHER INFORMATION

What PecFent contains

PecFent is available in two strengths: PecFent 100 micrograms/spray nasal spray solution and PecFent 400 micrograms/spray nasal spray solution.

- The active substance is fentanyl.
PecFent 100 or 400 micrograms/spray nasal spray, solution
Each ml of solution contains 1,000 micrograms (100 microgram strength) or 4,000 micrograms (400 microgram strength) fentanyl (as citrate).
1 spray (100 microliters) contains either 100 micrograms (100 microgram strength) or 400 micrograms (400 microgram strength) fentanyl.
- The other ingredients are pectin (E440), mannitol (E421), phenylethyl alcohol, propyl hydroxybenzoate (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, 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. Each PecFent bottle is supplied in a child resistant container.

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

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