

Important information about the safe use of PecFent® (fentanyl) Nasal Spray

Patient and Carer Guide

How PecFent® can help you manage breakthrough cancer pain

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PecFent[®] Patient and Carer Guide

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Please note: This guide is not a replacement for the Patient Information Leaflet (PIL) supplied in the PecFent[®] carton, which should also be read before you start to take your medication.

What is breakthrough cancer pain?

Many people who are suffering from cancer will experience regular pain. This ongoing and continuous pain is sometimes called “background pain”. However, people that experience background pain may also experience periods of particularly severe and intense pain that “breaks through” the regular or background pain. This is known as breakthrough cancer pain (BTcP).

Breakthrough cancer pain usually:

- Comes on very quickly
- Is severe and intense, “breaking through” your background pain relief medication
- Rarely lasts more than 30 minutes
- Is not controlled by normal background pain medication
- Can be predictable or unpredictable (and it can be brought on by activities such as walking, coughing or sneezing)

Because breakthrough cancer pain comes on so quickly and is very intense, it needs a specially designed medicine to tackle the pain, which is different to your background cancer pain medicine. The medicines for breakthrough pain are fast-acting and provide pain relief which lasts for about the same amount of time as an episode of breakthrough pain.

The experience of pain is different for everyone. It is therefore very important that you talk to the doctors and nurses looking after you, so that they can find the right type and dose of painkillers to control the type of pain you are experiencing. You shouldn't feel worried about saying that your pain is not properly controlled. Your doctors and nurses are there to help you.

What is PecFent[®]?

PecFent[®] contains a drug called fentanyl. This is a treatment for adults who must already be taking strong pain-relieving medicine (opioids) for their persistent background cancer pain, but require treatment for their breakthrough cancer pain

- PecFent[®] is only to be used for breakthrough cancer pain. PecFent[®] must not be used for other short-term pain. If you are not sure, talk to your doctor
- 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
- Fentanyl is absorbed quickly from the gel droplets through the lining of your nose into the blood stream

Please see the section called **How to take PecFent[®]** on page 7 of this booklet for a detailed description of how to take your medicine

If you need any more information or have any questions regarding the use of the nasal spray device and required safety precautions, please contact your healthcare provider and/or pharmacist.

Starting PecFent[®] and finding the right dose for you

Before taking PecFent[®] for the first time your doctor will explain how PecFent[®] should be taken to effectively treat your breakthrough cancer pain.

Ensure that you have received the proper information from your Health Care Provider and/or Pharmacist regarding the use of the nasal spray device and required safety precautions.

PecFent[®] should be used as instructed by your doctor/nurse.

Read the Patient Information Leaflet and this patient guide before starting treatment to:

- Make sure it is the right treatment for you
- To make sure that you understand how to use, store and dispose of the nasal spray device and the child resistant container
- You know how you should be taking PecFent[®] to effectively treat your breakthrough cancer pain

Ask your Health Care Provider and/or Pharmacist if you need more information or have any questions.

PecFent[®] is a treatment for adults who must already be taking strong pain-relieving medicine (opioids) daily for their persistent cancer pain, however, require treatment for their breakthrough cancer pain.

It is important that you remain on the medicine (opioids) that you are already taking to control your regular cancer pain.

PecFent[®] is only to be used for breakthrough cancer pain.

PecFent[®] must not be used for other short-term or long-term pain. If you are not sure, talk to your doctor.

If you have not been regularly taking or using a prescribed opioid medicine to control your persistent pain for at least one week, this medicine could cause severe side effects including

breathing difficulties.

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.

PecFent® should only be used by you, according to your doctor's instructions. It should not be used by anyone else as it could present a serious life-threatening risk to their health, especially to children.

PecFent® is available in two strengths. The cartons, child-resistant containers and bottle labels are colour-coded, so you can tell them apart. Your doctor or pharmacist can advise you about these.



Yellow carton
100 microgram/spray strength

Violet carton
400 microgram/spray strength

The starting dose of PecFent® is always 100 micrograms (even if your doctor is switching you from another fentanyl product). You may need to try a number of PecFent® doses over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will instruct you what to do. A dose may involve taking one spray (into one nostril) or two sprays (one into each nostril) to treat an episode of breakthrough pain. Ensure you follow your doctor's instructions.

In order to minimise the risk of side-effects, your doctor, or other healthcare professional, will monitor you closely whilst finding the

best dose for you. If you are not sure, talk to your doctor.

Once you've found the right dose

Once you and your doctor have found a dose of PecFent® that controls your breakthrough cancer pain (your personal optimal dose) you should take this dose no more than 4 times a day. You must leave at least 4 hours from taking your last dose before treating your next episode of breakthrough pain with PecFent®. You should not use more than the dose your doctor prescribes. If your doses are taken too often, or too close together, there is a greater risk of serious side-effects.

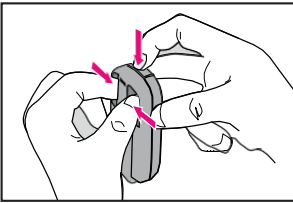
PecFent® is different from other medicines you may have used to treat your breakthrough pain. You must always use the dose of PecFent® prescribed by your doctor – this may be different from the one you have used with other medicines for breakthrough pain.

If you are not getting enough pain relief for your breakthrough cancer pain episode, this might indicate that your PecFent® 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.

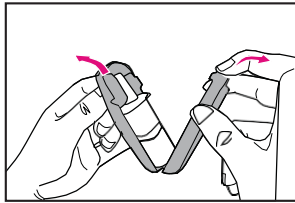
How to take PecFent®

PecFent® is contained in a clear glass bottle, fitted with a pump which delivers an exact dose of medicine with each spray. PecFent® is only to be used by spraying into your nostril. The PecFent® bottle must always be stored in the child-resistant container. Please see below instructions on how to open and close the child-resistant container:

OPEN

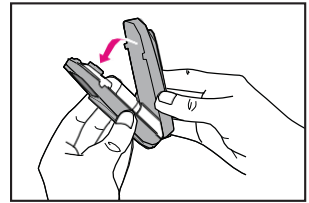


1. Insert fingers into rear cavities and squeeze while pushing down top button



2. Open

CLOSE



3. Close (listen for confirmation click)

Before administering a dose, the spray must be primed (prepared for use). After priming, the spray can deliver eight full sprays.

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) and aim the nasal spray away from you (and any other people)
3. 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)
4. 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)

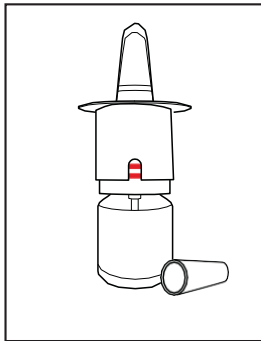


Figure 1

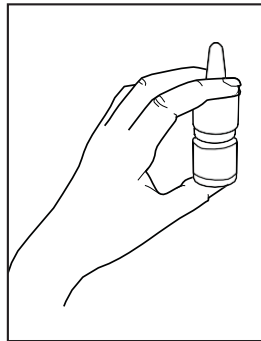


Figure 2

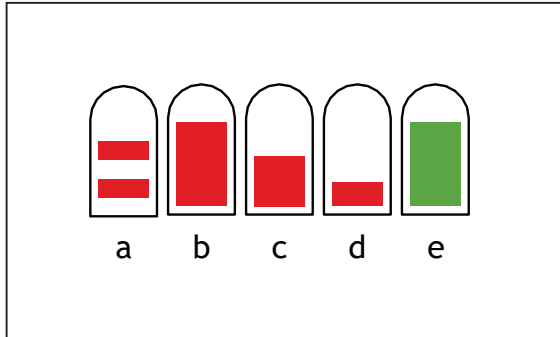


Figure 3

5. Repeat step 4 three times. As you repeat step 4, 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
6. Wipe the nozzle with a tissue and flush the tissue down the toilet
7. 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. If you have not used the bottle for 5 days, re-prime by spraying once. Discard the bottle 60 days after first opening
8. Write the date that you primed the PecFent[®] bottle in the space on the child-resistant container label

Using PecFent® for the first time

1. Check that there is green bar showing in the counting window (Figure 4), this confirms that the PecFent® bottle has been primed (see instructions on how to prime the bottle on page 8 of this booklet)
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 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)

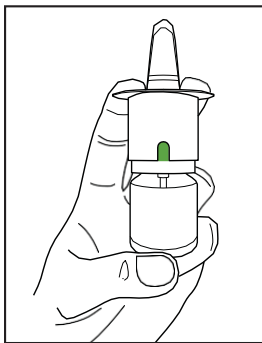


Figure 4



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, but do not trust this to mean the spray did not operate, instead 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
- 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

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

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

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

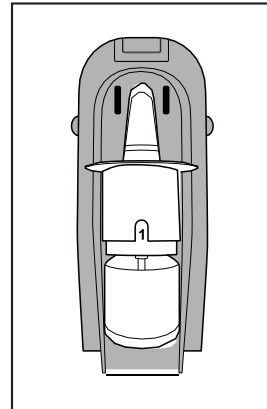


Figure 6

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).

After each spray:

- The click provides an audible signal that the spray has been administered

- The number on the counter moves forward by one count, providing a visual signal of how many sprays have been used

Once all 8 sprays have been used, the number “8” will appear in the counter window, which means that all eight sprays have been used. When the number “8” appears, you should not attempt to administer another spray from the bottle.

Please see the section called Requirements for Storing PecFent® on page 13 of this booklet for a detailed description of how to correctly store and dispose of this medicine.

Using a PecFent® bottle you have used before

- Do not use the bottle if more than 60 days have passed since you first used the spray (to help you remember, there is a space on the child-resistant container label for you to write the date of first use)
- Do not use the bottle if it is past the expiry date printed on the packaging
- Make sure there is a black number in the counting window then follow the section ‘Using PecFent® for the first time’ on page 10 of this booklet. If you have not used the bottle for 5 days, re-prime by spraying once
- 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

Requirements for storing PecFent®

PecFent® should be kept in the child-resistant container in a locked place away from other people, especially 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.

PecFent® contains a medicine that is attractive to people who abuse drugs such as narcotics and should therefore be stored in a secure location.

How to dispose of PecFent®

Partially used PecFent® bottles may contain enough medicine to be harmful or life-threatening to other people, especially children. Even if there is little or no medicine left in the bottle, PecFent® must be disposed of properly, according to the following steps:

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 finger 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 as follows:

- 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, and the counter will stay on number “8”

- Put the protective cap back on the spray bottle and put the bottle back in the child-resistant container

Dispose of the empty bottles in their child-resistant container as soon as possible by taking them back to the pharmacy.

Adverse effects which might be experienced

- If you have not been regularly taking or using a prescribed strong pain relief medication (opioid) to control your regular pain for at least 1 week before starting your breakthrough cancer pain medication, PecFent® could cause severe side-effects, including breathing difficulties. These may include an increased risk of breathing becoming dangerously slow and/or shallow, or even stop
- As with other similar pain medicines, PecFent® can cause some side-effects and does carry a risk of accidental overdose and a risk of abuse. Your healthcare provider should inform you how to minimise these risks
- If you suspect you are developing side-effects following the use of PecFent®, you should contact your doctor who will help you to ascertain whether the medication is suitable for you. If you are unsure, ask your healthcare provider
- PecFent® has similar side-effects to those associated with your strong pain-relieving medicine (opioids) for cancer pain. More information on these is detailed in the package leaflet
- If you do experience any of the side-effects listed there or experience any other effects taking PecFent®, inform your healthcare provider. They may be able to help reduce these while ensuring that you continue treatment
- You should not use more than the dose your doctor prescribes for any single breakthrough pain episode. If your doses are taken too often, or too close together, there is a greater risk of serious side-effects

- If you follow the instructions on how to take PecFent® and follow the advice of your healthcare provider on how many PecFent® doses to take, it is extremely unlikely that you will take too much. However, in the event of an overdose you may feel very drowsy, very dizzy and/or may feel short of breath with only slow or shallow breathing. In the event of an overdose, take the following steps:

Do not take any further doses of PecFent®:

- Tell someone nearby (another person in your house or your nurse/carer) what has happened
- Immediately contact your designated healthcare provider or other emergency medical help (e.g. an ambulance)
- Your nurse/carer should keep you awake by talking to you or shaking you gently now and again

If you think someone has taken PecFent® by accident seek emergency medical help immediately.

PecFent® contains an active substance in an amount that can be fatal to a child (and should not be used by anyone under 18).

Keep all nasal spray devices out of sight and reach of children even if you have finished with the device.

Inappropriate use of this medicine may lead to dependence. Inform your healthcare provider immediately if you think you are becoming dependent on PecFent® or your regular strong pain-relieving (opioid) medication.

The risk of developing a condition called serotonin syndrome may increase if you are taking PecFent® together with certain other medications. These medicines include antidepressants, medicines that are used for some types of psychiatric disorders, anti-sickness medications and other pain killers.

As with other similar pain medicines, PecFent® may interact with these medicines and you may experience a number and range of side-effects, details of which are described in the patient information leaflet.

You should call an ambulance or ask someone to call one immediately if you

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

If you experience nosebleeds or nasal discomfort, you should contact your doctor.

Tell your doctor if you have liver or kidney problems as this can affect the way in which your body breaks down the medicine.

If you do experience any of the side-effects listed on the patient information leaflet or experience any other side-effects which you think are related to taking PecFent[®], inform your healthcare provider. They may be able to help reduce these while ensuring that you continue treatment.

Reporting of side-effects

If you suspect you are developing any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in the package leaflet.

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA)

SFDA call center: 19999

Toll free phone: 8002490000

Fax: +966-11-2057662

E-mail: npc.drug@sFDA.gov.sa

Website: <http://ade.sFDA.gov.sa/>

Abdulrehman ALGosaibi G.T.C

Name: Abdulrahman Alharbi

Title: Pharmacovigilance Officer

Mobile: +966 556953934

Phone: +966 4793000

Email: aalharbi@aralgosaibico.com

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

Breathing difficulties

If you start to feel unusually drowsy, or your breathing becomes shallow and/or slow, you or your carer should immediately contact your doctor/ local hospital or an ambulance.

Pregnancy and breastfeeding

Do not use PecFent® if you are pregnant or might get pregnant, unless your healthcare provider has instructed you to do so.

Fentanyl can get into breast milk and may cause side-effects in the breastfed infant. Do not use PecFent® if you are breastfeeding.

You should not start breastfeeding within 5 days after the last dose of PecFent®.

Learning more – frequently asked questions

Q. When should I take PecFent®?

A. Take PecFent® as soon as an episode of breakthrough cancer pain begins (unless it is less than 4 hours since taking PecFent for your last breakthrough cancer pain episode, or, you have already taken 4 doses of PecFent within 24 hours).

Q. What should I do if I experience any side-effects when taking PecFent®?

A. If you experience any side-effects when taking PecFent®, you should speak to your doctor or nurse who may be able to resolve them while still controlling your breakthrough cancer pain. Additionally, if you start to feel unusually sleepy, or if your breathing becomes slow or shallow, you or your carer should immediately contact your doctor or local hospital for emergency help

Q. What is the maximum number of breakthrough cancer pain episodes I can treat with PecFent® in a single day?

A. Once you and your doctor have found a dose of PecFent® that controls your breakthrough pain you should take this dose no more than 4 times in any 24-hour period

Q. How long should I leave between treating episodes of breakthrough pain?

A. It is important to leave at least 4 hours before treating another episode of breakthrough pain

Q. What should I do if I take an overdose?

A. If you think you have taken an overdose of PecFent®, immediately contact your local hospital for emergency help

Q. What should I do if I am still experiencing breakthrough cancer pain?

A. You should consult your doctor or nurse for advice

Q. Are other medicines available to help control my breakthrough cancer pain?

A. There are a range of medicines available for controlling breakthrough cancer pain. Your doctor or nurse will be able to advise you about the most effective medicine for your needs.

Useful contact details

If you have any questions about PecFent® or your pain management, please contact your health professional.

Doctor:

Address:

Telephone:

Nurse:

Address:

Telephone:

Please consult the Patient Information Leaflet (PIL) in the PecFent® product package. Your healthcare provider can provide you with a copy.

For extra copies please contact: Abdulrehman ALGosaibi,
G.T.C

Tel: +966 556953934

email: aalharbi@aralgosaibico.com

Marketing Authorisation Holder:

Kyowa Kirin Holdings B.V.

Bloemlaan 2

2132NP Hoofddorp, The Netherlands

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