

Physician's guide to prescribing PecFent[®]



PecFent


FENTANYL NASAL SPRAY



Dear Prescriber,

PecFent is indicated for the treatment of breakthrough cancer pain in opioid-tolerant patients. It contains PecSys[®], a gelling technology that prevents running/dripping and modulates the absorption of fentanyl to provide rapid and consistent delivery of fentanyl. During three phase III clinical studies, 506 patients were treated with PecFent for up to 159 days across 45,599 breakthrough cancer pain episodes.¹

The purpose of this brochure is to provide additional information on the safe and appropriate use of PecFent including:

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- 1. Indication**
 - 2. Dosing and titration**
 - 3. What you must do before prescribing PecFent**
 - 4. Prescribing checklist**
 - 5. Storage and safety**
 - 6. Disposal**
 - 7. Warnings**
 - 8. Additional resources**

It summarises important information from the Summary of Product Characteristics (SPC) but is not intended to replace it. Before prescribing PecFent for the first time, please read the following information.



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Indication

- PecFent should only be prescribed by physicians who are knowledgeable and skilled in the use of opioids to treat cancer pain
- PecFent prescribers must select patients according to the strict criteria listed in the prescribing checklist (see section 3 What you must do before prescribing PecFent)
- Physicians should carefully monitor all patients for whom they have prescribed PecFent to ensure that they understand the potential risks of fentanyl therapy and that they are using the product in an appropriate manner
- PecFent is indicated for the management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough cancer pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain
- Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer
- PecFent is not licensed to treat any other type of short-term pain
- Patients who take PecFent must already be receiving maintenance opioid therapy for persistent background pain as the doses licensed for PecFent are likely to be dangerous to opioid-naïve patients

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Dose and titration

PecFent is available in two strengths:

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

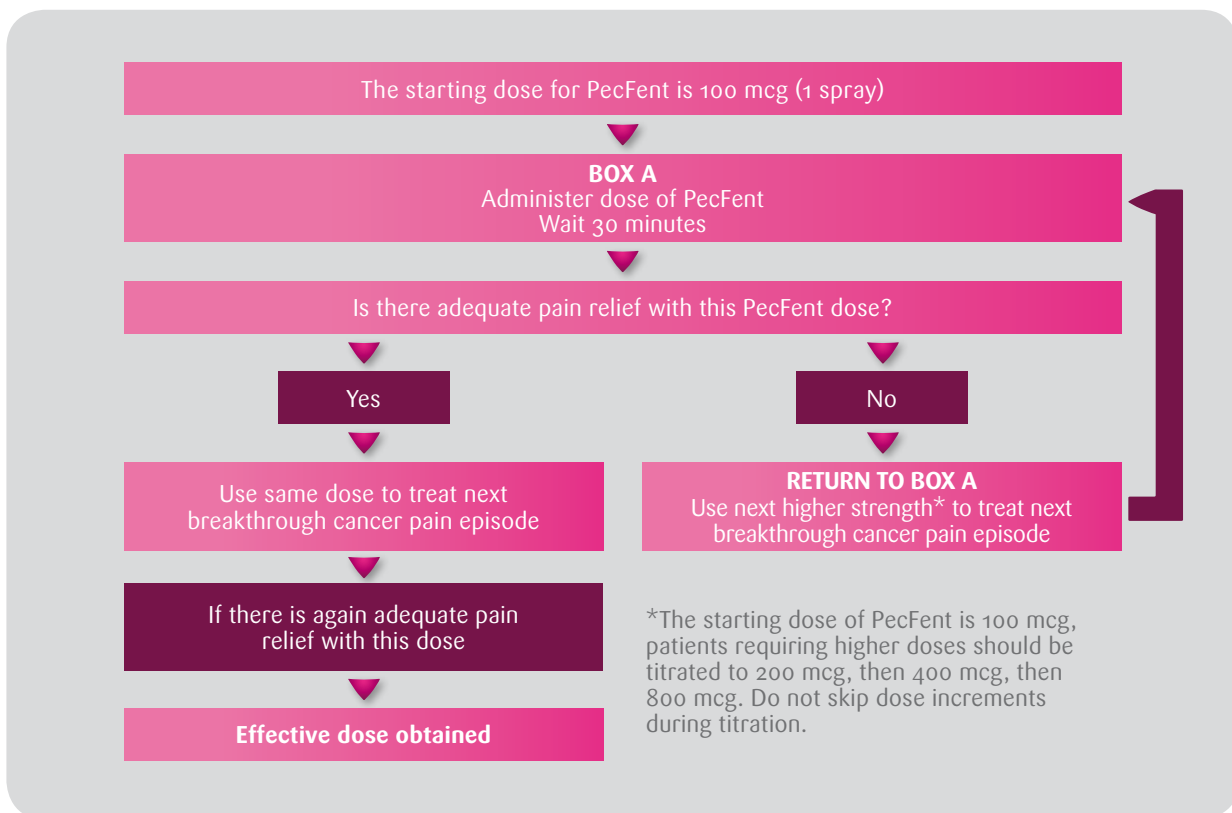


PecFent can deliver 100, 200, 400 and 800 mcg doses as follows:

Pack colour	Dose required (mcg)	Product strength (mcg/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

- Bioavailability between all products for breakthrough cancer pain differs significantly, therefore when switching to PecFent from another fentanyl product, independent dose titration is required
- Do not calculate PecFent dose strengths based on comparison with other fentanyl products the patient is already receiving (including other fentanyl nasal sprays)
- Patients should always be initiated on a dose of 100 mcg (one spray) and then titrated to an “effective dose” using the titration scheme outlined below
- 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

Figure 1: Titration flow chart



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What you must do before prescribing PecFent

- Before prescribing, ensure that you are familiar with the PecFent SPC (available at www.PecFent.com/uk/spc)
- Please familiarise yourself with the PecFent instructions for use and ensure you are able to demonstrate the correct handling and use of the PecFent nasal spray to patients
- Please talk through the comprehensive Patient Brochure with your patients and make sure they take a copy with them
- Please use the following checklist for prescribers

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PecFent prescribing checklist

Required actions before PecFent is prescribed:

- Patient is on a suitable opioid maintenance regimen (see page 2)
- If an initial prescription, the dose is 100 mcg (1 spray)
- Patient is given instructions on how to use the nasal spray
- Patient is familiarised with the Patient Information Leaflet and takes a copy with them
- Patient is familiarised with the Patient Brochure and takes a copy with them
- Patient and carers are advised about the signs of fentanyl overdose and the need for immediate medical assistance
- Patient and carers are advised on secure storage (keep out of the sight and reach of children; after each use return the spray to the child-resistant container)
- Patient and carers are shown how to open and close the child-resistant container (as described in the Patient Information Leaflet and Patient Brochure)
- Patient and carers are advised on the correct disposal of PecFent nasal spray

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Storage and safety

PecFent is contained in a clear glass bottle, fitted with a metering pump. Delivery of a spray of PecFent to the nose is not always detectable to the patient, therefore, as a safety feature, the pump has been fitted with a spray counter that clicks when a dose is emitted.

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

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.

- PecFent should only be handled by patients or their carers. Patients should be advised not to let anyone else handle or use the product
- After each use, PecFent must be returned to the child-resistant container for storage
- Please ensure patients understand that in order to prevent theft and misuse, they should store PecFent in a suitably secure place

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Disposal

- PecFent nasal spray must be disposed of properly, in accordance with local regulations. All unused, partly used or empty nasal sprays that are no longer required should be returned to the local pharmacist in the child-resistant container for proper disposal

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- Unintentional exposure to PecFent is considered a medical emergency and a potentially life-threatening event
- Ensure your staff are aware of the signs of fentanyl overdose and the appropriate protocol for its management
 - Signs of toxicity are:
 - Deep sedation
 - Respiratory depression
 - Ataxia
 - Convulsions
- Any of these events connected with PecFent use requires immediate medical assistance
- Patients and their carers should be made aware of these signs, understand their potential seriousness and be appropriately advised on what to do in the event of an emergency
- If a child is accidentally exposed to the product, immediate medical attention should be sought
- Bear in mind the potential for abuse of the product

Please note that the following additional educational guides have been developed:

- Patient Brochure (How to use PecFent)
- A video guide on how to use your PecFent
- A Pharmacist's guide to dispensing PecFent (includes a dispensing checklist)

These are available on the PecFent website (www.PecFent.com).

This material can also be requested from the Archimedes Pharma Medical Information Department:

Tel: +44 (0) 118 931 5094

Fax: +44 (0) 118 931 5056

Email: medicalinformationuk@archimedespharma.com

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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Archimedes Pharma, by phone at +44 (0) 1582 766 339 or by email at PVArchimedesPM@akos.co.uk.

ABBREVIATED PRESCRIBING INFORMATION. Please refer to the full Summary of Product Characteristics (SPC) before prescribing. **PecFent ▼ 100 micrograms and 400 micrograms/spray, nasal spray solution (fentanyl pectin nasal spray):** Each ml of solution contains either 1,000 µg or 4,000 µg fentanyl (as citrate), delivered using the PecSys gelling system. **Indication:** Management of breakthrough pain (BTP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain. **Dosage and Administration:** Treatment should be initiated by and remain under the supervision of a physician experienced in the management of opioid therapy in cancer patients. PecFent should be titrated to an effective dose that provides adequate analgesia and minimises adverse reactions. **Initial Dose:** One 100 µg spray, patients must wait at least 4 hours before treating another episode of BTP with PecFent. **Titration:** If the initial dose is unsuccessful, a higher dose of two 100 µg sprays (one in each nostril) can be used for the next BTP episode. If this dose is not successful, the patient may be prescribed a bottle of PecFent 400 µg/spray and instructed to change to one 400 µg spray for their next episode of pain. If this dose is not successful, the patient may be instructed to increase to two 400 µg sprays (one in each nostril). Once an effective dose is reached, it should be confirmed for two consecutively treated episodes of BTP. **Maintenance:** Patients should continue to take their established effective dose up to a maximum of 4 doses per day. **Dose readjustment:** The dose of PecFent should only be increased if the current dose fails to adequately treat BTP for several consecutive episodes. Review the background opioid therapy if the patient consistently presents with more than 4 BTP episodes per 24 hours. If adverse reactions are intolerable or persistent reduce PecFent dose. Discontinuation of therapy: PecFent should be discontinued immediately if the patient no longer experiences BTP episodes. Treatment for background pain should be kept as prescribed. If all opioid therapy is to be discontinued, the patient must be closely followed by the doctor as gradual downward titration is necessary to avoid withdrawal effects. **Contraindications:** Hypersensitivity to the active substance or excipients. Use in opioid naïve patients. Severe respiratory depression or severe obstructive lung conditions. **Interactions:** Potential interactions may occur when PecFent is given concurrently with agents that affect CYP3 A4 activity. The use of other central nervous system depressants may produce additive depressant effects. PecFent is not recommended for use in patients who have received MAO inhibitors within the previous 14 days. Concomitant

use of partial opioid agonists/antagonists is not recommended. Concomitant use of nasally administered vasoconstrictive decongestants during titration is not recommended. Concomitant use of other nasally administered products should be avoided within 15 minutes of dosing with PecFent. **Precautions:** PecFent contains fentanyl in an amount that can be fatal to a child, therefore it should be kept out of the reach and sight of children. Tolerance and dependence may develop upon repeated administration of opioids such as fentanyl. Fentanyl use has a clinically significant risk of respiratory depression, however chronic opioid use lowers this risk. Fentanyl use may cause more serious adverse reactions in patients with chronic obstructive pulmonary disease. PecFent should be administered with extreme caution in patients with increased intracranial pressure. Intravenous fentanyl may produce bradycardia, therefore PecFent should be used with caution in patients with pre-existing bradyarrhythmias; careful consideration should also be given to patients with hypovolaemia and hypotension. PecFent should be administered with caution to patients with hepatic or renal impairment; when administered intravenously the clearance of fentanyl has been shown to be altered in hepatic and renal impairment due to alterations in metabolic clearance and plasma proteins. The safety and efficacy of PecFent in children aged below 18 years have not been established. **Pharmacodynamic Effects:** Analgesic effects in BTP have been demonstrated in RCTs from 5 minutes after dosing, reaching clinically meaningful levels from 10 minutes. Use in 355 patients across 42,227 episodes of BTP for durations of up to 159 days showed infrequent need for additional (rescue) medication (6.0% of episodes) or dose increase (<10% of patients). **Side Effects:** Typical opioid adverse reactions are to be expected with PecFent, the most serious potentially being respiratory depression, circulatory depression, hypotension and shock; all patients should be monitored for these. **Common:** disorientation, dysgeusia, dizziness, somnolence, headache, epistaxis, rhinorrhoea, nasal discomfort, vomiting, nausea, constipation and pruritus. Prescribers should consult the SPC in relation to other side effects. **Presentation and Cost:** One bottle of PecFent 100 or 400 mg/ml (8 sprays) £30.40, one pack (four bottles of PecFent 100 or 400 mg/ml (32 sprays)) £121.60. **Marketing Authorisation Numbers:** EU EU/1/10/644/001-4. **Marketing Authorisation Holder:** Archimedes Development Ltd, Nottingham, NG7 2TN, UK. **Legal Category:** CD (Sch2) POM. **Date of PI preparation:** September 2010. For further information please contact: Archimedes Pharma UK Ltd, 250 South Oak Way, Green Park, Reading, Berkshire, RG2 6UG, UK.

References:

1. Archimedes Pharma PecFent Data on File 007.

NAS0507/003

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