PecFent®

FENTANYL (CITRATE) NASAL SPRAY

Prescriber Guide

This is an information document that should be referred to in conjunction with important information contained within the PecFent Physician's Prescribing Information (PPI).

This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important risks and it is advised therefore that it be read carefully before prescribing/dispensing/administering the product.

Please consult the PPI for full prescribing information.

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Contents

This guide contains specific information on the safe prescribing and use of PecFent (fentanyl citrate). This guide contains the following information:

1 Therapeutic indications

- PecFent is indicated for the management of breakthrough pain (BTP) in adults who are already receiving maintenance opioid therapy for chronic cancer pain.
- Breakthrough 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 micrograms 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.

2 Important information

1. Treatment with PecFent should be initiated by and remain under the supervision of a physician experienced in the management of opioid therapy in cancer patients, in particularly regarding transition from hospital to home.
2. Physicians should keep in mind the potential for abuse of fentanyl.
3. PecFent should not be prescribed to or used by children and adolescents aged below 18 years as the safety and efficacy of such use have not yet been established. The indication stated in the PPI must be adhered to.
4. Abuse or intentional misuse of PecFent may result in overdose and/or death.

Cases of off-label use, misuse, abuse, addiction and overdose must be reported (refer to back cover).

3 Dosing

PecFent should be titrated to an "effective" dose that provides adequate analgesia and minimises adverse reactions without causing undue (or intolerable) adverse reactions, for two consecutively treated episodes of BTP.

The efficacy of a given dose should be assessed over the ensuing 30 minute period.

Patients should be carefully monitored until an effective dose is reached.

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

Patients should not use more than 4 doses per day; Patients should wait at least 4 hours after a dose before treating another BTP episode with PecFent.

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

Dose required (micrograms)	Product strength (micrograms)	Amount
100	100	One spray administered into one nostril
200	100	One spray administered into each nostril
400	400	One spray administered into one nostril
800	400	One spray administered into each nostril

Initial dose

The initial dose of PecFent to treat episodes of BTP is always 100 micrograms (one spray), even in patients switching from other fentanyl containing products for their BTP.

Titration

Patients whose initial dose is 100 micrograms and who need to titrate to a higher dose due to a lack of effect can be instructed to use two 100 microgram sprays (one in each nostril) for their next BTP episode.

If this dose is not successful, the patient may be prescribed a bottle of PecFent 400 micrograms/spray and instructed to change to one 400 microgram spray for their next episode of pain.

If this dose is not successful, the patient may be instructed to increase to two 400 microgram sprays (one in each nostril).

From treatment initiation, patients should be closely followed and the dose titrated until an effective dose is reached and confirmed for two consecutively treated episodes of BTP.

4 Overdose

Symptoms of PecFent overdose are similar in nature to those of intravenous fentanyl and other opioids.

Overdose with PecFent may lead to respiratory depression or coma.

Immediate management of opioid overdose includes ensuring a patent airway, physical and verbal stimulation of the patient, assessment of the level of consciousness, ventilatory and circulatory status, and assisted ventilation (ventilatory support) if necessary.

For treatment of overdose (accidental ingestion) in the opioid-naïve person, intravenous access should be obtained and naloxone or other opioid antagonists should be employed as clinically indicated.

Cases of Cheyne Stokes respiration have been observed in case of fentanyl overdose, particularly in patients with history of heart failure.

5 Opioid Use Disorder (abuse and dependence)

Tolerance and physical and/or psychological dependence may develop upon repeated administration of opioids such as fentanyl. Repeated use of PecFent may lead to Opioid Use Disorder (OUD).

Patients who are at risk of abuse and misuse of PecFent, must be identified and monitored before and during the treatment with PecFent to identify the key features of OUD: distinguishing features of opioid related side effects and opioid use disorder.

Monitoring for signs of drug-seeking behavior (e.g. too early requests for refills), review of concomitant opioids and psycho-active drugs (like benzodiazepines).

The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).

When a patient with OUD is identified, therapy should be tailored accordingly, consider a consultation with an addiction specialist.

6 Discuss

With the patient and/or carer about:

- Treatment management and risks of abuse and dependence
- Need for periodic review by prescribers
- Encouragement for reporting of any issue with the management of the treatment

Patients must be critically selected and consulted about:

- Instructions for use of PecFent
- Never sharing the PecFent medication or diverting the purpose of its use.
- Updated label information including hyperalgesia, use in pregnancy, drug interactions such as with benzodiazepines, iatrogenic addiction, withdrawal and dependence.

Prescriber's checklist

The checklist below includes required actions before prescribing PecFent. Please complete all of the following before prescribing PecFent:

- Ensure that all elements of the approved indication are fulfilled.
- Provide the patient and/or carer with instructions for using PecFent.
- Ensure the patient reads the Patient Information Leaflet.
- Inform the patient of the Patient Alert Card attached to the package.
- Describe the risks associated with using more than the recommended amount of PecFent.
- Explain the use of the dose monitoring card.
- Advise the patients on the signs of fentanyl overdose and the need for immediate medical assistance.
- Emphasize secure storage and the need to keep out of the reach and sight of children.
- Remind the patient and/or caregiver that they should consult a physician if they have any questions or concerns about how to use PecFent or about the associated risks of misuse and abuse.

Reporting adverse events
Healthcare professionals are asked to report any suspected adverse reactions.
Adverse events can be reported to the Ministry of Health using the online form for adverse event reporting which can be found on the **Ministry of Health website:** www.health.gov.il or by using the **following link:** https://sideeffects.health.gov.il/.
Adverse events can be also reported to Medison Pharma Ltd.
by email: PVIsrael@medisonpharma.com or **fax:** 03-9234218.

This guide was reviewed and approved by the Ministry of Health in Apr-2023.

Patient Alert Card including dose monitoring is attached to the package and available on www.health.gov.il or by calling 03-9250250.

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