PecFent®

FENTANYL (CITRATE) NASAL SPRAY

Pharmacist guide

Important Risk Minimisation Information for Pharmacists

This is an information document that should be referred to in conjunction with important information contained within the PecFent Physician's Prescribing Information (PPI) and Patient Information Leaflet (PIL).
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 dispensing the product.
Please consult the PPI for full prescribing information.

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Therapeutic indications and important information

- 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.
- 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.
- PecFent is not interchangeable with other fentanyl products.
- 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.
- Abuse or intentional misuse of PecFent may result in overdose and/or death.
- Overdose with PecFent may lead to respiratory depression or coma.

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

Dosing

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.

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 monitored 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).

When a patient with OUD is identified, the patient's attending physician should be contacted.

Converse with the patient 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

Counsel the patients on:

- Instructions for use of PecFent (as explained in the PIL).
- Prevention of theft and misuse of PecFent – the patient must keep the PecFent in a safe place to avoid misuse and diversion.

Pharmacist's dispensing checklist

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

- 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.

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 approved and reviewed 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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