

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

Fentanyl-Piramal

חברת פארמה מדיס מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

- For analgesic action of short duration during anesthetic periods (premedication, induction and maintenance) and in the immediate postoperative period, as need arises.
- As a narcotic analgesic supplement in general or regional anesthesia.
- For administration with a neuroleptic [such as droperidol] as an anesthetic premedication, for the induction of anesthesia, and as an adjunct in the maintenance of general and regional anesthesia.
- For use as an anaesthetic agent with oxygen in selected, high-risk patients (open heart surgery or certain neurological or orthopedic procedures).
- By the epidural route for the postoperative management of pains following general surgical procedures and cesarean sections and as adjunct to general anesthesia.

מרכיב פעיל: FENTANYL (AS CITRATE) 0.05 MG/ML
צורת המתן של התכשיר : SOLUTION FOR INJECTION

להלן העדכונים העיקריים בעלון לצרכן (במתכונת עלון לרופא):

4.4 Warnings:

Tolerance and Opioid use disorder (abuse and dependence, tolerance and potential for abuse)

Drug dependence, tolerance and potential for abuse

Tolerance, physical dependence, and psychological dependence may develop upon repeated administration of opioids

Repeated use of opioids may lead to Opioid use disorder (OUD). Abuse or intentional misuse of opioids may result in overdose and/or death. 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

4.5 Interaction with other medicinal products and other forms of interaction

Effect of other drugs on fentanyl



4 Fierberg St. P.O.Box 2820 Holon 5812801 Israel
Tel: +972-(0)72-2555533 +972-(0)3-5057906
Fax: +972-(0)72-2555534 +972-(0)3-5059865
eMail: info@pharmamedis.com

Central Nervous System (CNS) depressants

The use of opioid premedication, barbiturates, benzodiazepines or related drugs, neuroleptics, general anaesthetics, gabapentinoids (gabapentin and pregabalin), and other non-selective CNS depressants (e.g. alcohol) may enhance or prolong the respiratory depression of fentanyl.

השינויים המודגשים ברקע צהוב מהווים החמרה. בעלון בוצעו שינויים נוספים אשר מהווים תוספת מידע.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://israeldrugs.health.gov.il/#!/byDrug>

ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת פארמה-מדיס, פיירברג 4 חולון.

בברכה,

מירי חזן
רוקחת ממונה