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טל' 09-9591111
09-9583636

נוהל להגשת בקשות לרישום, שינוי וחידוש תכשירים רפואיים למחלקה לרישום תכשירים
אוגוסט 2012

נספח 16 טפסים להגשת החמרות בעלונים

נוהל להגשת בקשות לרישום, שינוי וחידוש תכשירים רפואיים למחלקה לרישום תכשירים
אוגוסט 2012

הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 29-10-2014
שם תכשיר באנגלית ומספר הרישום: FENTANYL JANSSEN 254121376
שם בעל הרישום: J-C HEALTH CARE LTD.

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
Dosage and administration	To avoid bradycardia, it is recommended to administer a small intravenous dose of an anti-cholinergic just before induction. *[Droperidol may be given to prevent nausea and vomiting.]* - ***Use as an analgesic supplement to general anaesthesia*** Low dose: 2 µg/kg Fentanyl in small doses is most useful for minor, but painful, surgery. -- *Use in the elderly* As with other opioids, the dose should be reduced in elderly or debilitated patients. - *Use in children* For induction and maintenance in children aged 2-12 years, a dose of 2-3 µg/kg is recommended.	To avoid bradycardia, it is recommended to administer a small intravenous dose of an anti-cholinergic just before anesthetic induction. ~~*[Droperidol may be given to prevent nausea and vomiting.]*~~ - ***Use as an analgesic supplement to general an~~a~~esthesia*** Low dose: 2 µg/kg Fentanyl in small doses is most useful for minor, ~~but painful,~~ surgery. **Special populations** - ~~*Use in the elderly*~~ *Elderly and debilitated patients* As with other opioids, the initial dose should be reduced in elderly (>65 years of age) and in ~~or~~ debilitated patients. The effect of the initial dose should be taken into account in determining supplemental doses. - ~~*Use in children*~~ *Pediatrics* For induction and maintenance in children aged 2-12 years, a dose of 2-3 µg/kg is recommended.

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Obese Patients In obese patients there is a risk of overdosing if the dose is calculated based on body weight. Obese patients should be dosed based on estimated lean body mass rather than on body weight only. *Renal Impairment* In patients with renal impairment reduced dosing of fentanyl should be considered and these patients should be observed carefully for signs of fentanyl toxicity (see Pharmacokinetic properties).		
As with all potent opioids , ~~R~~respiratory depression is dose related and can be reversed by a specific ~~narcotic~~ opioid antagonist ~~such as naloxone~~, but additional doses ~~of the latter~~ may be necessary because the respiratory depression may last longer than the duration of action of the opioid antagonist. Profound analgesia is accompanied by marked respiratory depression, which can persist or recur in the postoperative period. Therefore, patients should remain under appropriate surveillance. Resuscitation equipment and ~~narcotic~~ opioid antagonists should be readily available. Hyperventilation during an~~a~~esthesia may alter the patient's responses to CO_2, thus affecting respiration postoperatively. **Interaction with neuroleptic** If Fentanyl is administered with a neuroleptic, ~~*[such as droperidol],*~~ the user should be familiar with the special properties of each drug, particularly the difference in duration of action. When such a combination is used, there is a higher incidence of hypotension. Neuroleptics can induce extrapyramidal symptoms that can be controlled with anti-Parkinson agents.	Rrespiratory depression is dose related and can be reversed by a specific narcotic antagonist such as naloxone, but additional doses of the latter may be necessary because the respiratory depression may last longer than the duration of action of the opioid antagonist. Profound analgesia is accompanied by marked respiratory depression, which can persist or recur in the postoperative period. Therefore, patients should remain under appropriate surveillance. Resuscitation equipment and narcotic antagonists should be readily available. Hyperventilation during anaesthesia may alter the patient's responses to CO2, thus affecting respiration postoperatively. If Fentanyl is administered with a neuroleptic, [such as droperidol], the user should be familiar with the special properties of each drug, particularly the difference in duration of action. When such a combination is used, there is a higher incidence of hypotension. Neuroleptics can induce extrapyramidal symptoms that can be controlled with anti-Parkinson agents.	warnings and precautions
There are no adequate data from the use of Fentanyl in pregnant women. Fentanyl can cross the placenta in early pregnancy. Studies in animals have shown some reproductive toxicity (see ~~Section 5.3, Preclinical safety data~~ Non-clinical Information).). The potential risk for humans is unknown. Administration (intramuscular (IM) ~~I.M.~~ or I~~.~~V~~.~~) during childbirth (including cesarean section) is not recommended because Fentanyl	There are no adequate data from the use of Fentanyl in pregnant women. Fentanyl can cross the placenta in early pregnancy. Studies in animals have shown some reproductive toxicity (see Section 5.3, Preclinical safety data).). The potential risk for humans is unknown. Administration (I.M. or I.V.) during childbirth (including cesarean section) is not recommended because	Pregnancy, Breast-feeding and fertility

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crosses the placenta and may suppress spontaneous respiration in the newborn period ~~because the fetal respiratory center is particularly sensitive to opiates~~. If Fentanyl is ~~nevertheless~~ administered, assisted ventilation equipment must be immediately available for the mother and infant if required. . ~~an antidote for the child should always be at hand. .~~An opioid antagonist for the child must always be available. **Breast feeding** Fentanyl is excreted into human milk. Therefore, ~~nursing~~ breast-feeding or use of expressed breast milk is not recommended for 24 hours following the administration of this drug. The risk/benefit of breastfeeding following fentanyl administration should be considered. **Fertility** There are no clinical data on the effects of fentanyl on male or female fertility. In animal studies, some tests on rats showed reduced female fertility at maternal toxic doses (see Non-clinical Information).	Fentanyl crosses the placenta and because the fetal respiratory center is particularly sensitive to opiates. If Fentanyl is nevertheless administered, an antidote for the child should always be at hand. Fentanyl is excreted into human milk. Therefore, nursing is not recommended for 24 hours following the administration of this drug. The risk/benefit of breastfeeding following fentanyl administration should be considered.	
Patients should only drive or operate a machine if sufficient time has elapsed (at least 24 hours) after the administration of Fentanyl.	Patients should only drive or operate a machine if sufficient time has elapsed after the administration of Fentanyl.	Effects on ability to drive and use machines
Throughout this section, adverse reactions are presented. Adverse reactions are adverse events that were considered to be reasonably associated with the use of fentanyl citrate based on the comprehensive assessment of the available adverse event information. A causal relationship with fentanyl citrate cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.		Adverse Reactions

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An overdosage of Fentanyl manifests itself as an extension of its pharmacologic actions. Respiratory depression which can vary in severity from bradypnea to apnea may occur. ~~Depending on the individual sensitivity, the clinical picture is determined primarily by the degree of respiratory depression, which varies from bradypnea to apnea.~~ *Treatment* In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be assisted or controlled as indicated. A specific ~~narcotic~~ opioid antagonist, ~~such as naloxone~~, should be used as indicated to control respiratory depression. This does not preclude the use of more immediate countermeasures. The respiratory depression may last longer than the effect of the antagonist; additional doses of the latter may therefore be required.	An overdosage of Fentanyl manifests itself as an extension of its pharmacologic actions. Depending on the individual sensitivity, the clinical picture is determined primarily by the degree of respiratory depression, which varies from bradypnea to apnea. *Treatment* In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be assisted or controlled as indicated. A specific narcotic antagonist, such as naloxone, should be used as indicated to control respiratory depression. This does not preclude the use of more immediate countermeasures. The respiratory depression may last longer than the effect of the antagonist; additional doses of the latter may therefore be required.	Overdose
Wear gloves while opening ampule Accidental dermal exposure should be treated by rinsing the affected area with water. Avoid use of soap, alcohol, and other cleaning materials that may cause chemical or physical abrasions to the skin		Instructions for use/handling

מצ״ב העלון שבו מסומנות ההחמרות המבוקשות על רקע צהוב
שינויים שאינם בגדר החמרות סומנו (בעלון) בטקסט ירוק

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