PRESCRIBING INFORMATION

FENTRA® Injection IM/IV

(Fentanyl Citrate Injection USP)

فینٹرا انجکشن آئی ایم / آئی وی

COMPOSITION:
Fentra 2ml Injection
Each ml contains:
Fentanyl as citrate…USP...0.05mg
Fentra 5ml Injection
Each ml contains:
Fentanyl as citrate…USP...0.05mg

DESCRIPTION:
Fentra (Fentanyl Citrate) Injection is a sterile, non-pyrogenic solution for intravenous or intramuscular use as a potent narcotic analgesic. Each ml contains fentanyl citrate equivalent to 50 mcg (0.05 mg) fentanyl base in Water for Injection. Fentra (Fentanyl Citrate) injection contains no preservative.

PHARMACOLOGY:
Fentra (Fentanyl Citrate) is a narcotic analgesic. A dose of 100 mcg (0.1 mg)(2 ml) is approximately equivalent in analgesic activity to 10 mg of morphine or 75 mg of meperidine.
The principal actions of therapeutic value are analgesia and sedation. Fentanyl appears to have less emetic activity than either morphine or meperidine. Clinically no significant histamine release occurs with fentanyl.
Fentra (Fentanyl Citrate) injection preserves cardiac stability and blunts stress related hormonal changes at higher doses.
The pharmacokinetics of fentanyl can be described as a three-compartment model, with a distribution time of 1.7minutes, redistribution of 13minutes and a terminal elimination half-life of 219 minutes. The volume of distribution for fentanyl is 4 ml/kg. Fentra (Fentanyl Citrate) injection plasma protein binding capacity increases with increasing ionization of the drug between plasma and the central nervous system. It accumulates in skeletal muscle and fat is released slowly into the blood.
Fentanyl, which is primarily transformed in the liver, demonstrates a high first pass clearance and releases approximately 75% of an intravenous dose in urine, mostly as metabolites with less than 10% representing the unchanged drug. Approximately 9% of the dose is recovered in the feces, primarily as metabolites.
The onset of action of fentanyl is almost immediate when the drug is given intravenously; The usual duration of action of the analgesic effect is 30 to 60 minutes after a single intravenous dose of upto 100 mcg (0.1 mg) (2 ml). The peak respiratory depressant effect of a single intravenous dose of fentanyl citrate is noted 5 to 15 minutes following injection.
Following intramuscular administration, the onset of action is from seven to eight minutes, and the duration of action is one to two hours. As with longer acting narcotic analgesics, the duration of the respiratory depressant effect of fentanyl may be longer than the analgesic effect.

INDICATIONS:
Fentanyl Citrate Injection is indicated:
- For analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room)as the need arises.
- For use as a narcotic analgesic supplement in general or regional anesthesia.
- For the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- For use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

DOSAGE AND ADMINISTRATION:
Dosage should be individualized. Some of the factors to be considered in determining the dose are age, body weight,physical status, and underlying pathological condition, use of other drugs, type of anesthesia to be used and the surgical procedure involved. Dosage should be reduced in elderly or debilitated patients. Vital signs should be monitored routinely.
Premedication
Premedication (to be appropriately modified in the elderly, debilitated and those who have received other depressant drugs)-50 to 100mcg (0.05 to 0.1mg) (1 to 2ml) may be administered intramuscularly 30 to 60 minutes prior to surgery.
As a General Anesthetic
Fentra (Fentanyl Citrate) doses of 50 to 100 mcg/kg (0.05 to 0.1 mg/kg) (1 to 2 ml/kg) may be administered with oxygen and a muscle relaxant. This technique has been reported to provide anesthesia without the use of additional anesthetic agents. In certain cases, doses up to 150mcg/kg (0.15 mg/kg) (3 ml/kg) may be necessary to produce this anesthetic effect.
Adjunct to Regional Anesthesia
50 to 100mcg (0.05 to 0.1mg) (1 to 2ml) may be administered intramuscularly or slowly intravenously, over one to two minutes, when additional analgesia is required.
Postoperatively (recovery room)
50 to 100 mcg (0.05 to 0.1mg) (1 to 2ml) may be administered intramuscularly for the control of pain, tachypnea and emergence delirium. The dose may be repeated in one to two hours as needed.
Usage in Children
For induction and maintenance in children 2 to 12 years of age, a reduced dose as low as 2 to 3 mcg/kg is recommended.

DOSAGE RANGES:
Low dose-2 mcg/kg (0.002 mg/kg) (0.04 ml/kg).
Fentanyl in small doses is most useful for minor, but painful, surgical procedures.
Moderate dose-2 to 20 mcg/kg (0.002 to 0.02 mg/kg) (0.04 to 0.4 ml/kg).
Where surgery becomes more major, a larger dose is required.
High dose-20 to 50 mcg/kg (0.02 to 0.05 mg/kg) (0.4 to 1 ml/kg).
During open heart surgery and certain more complicated neurosurgical and orthopedic procedures where surgery is more prolonged,

CONTRAINDICATIONS:
Fentra (Fentanyl Citrate) Injection is contraindicated in patients with known intolerance to the drug.

WARNINGS:
Fentra (Fentanyl Citrate) Injection SHOULD BE ADMINISTERED ONLY BY PERSONS SPECIFICALLY TRAINED IN THE USE OF INTRAVENOUS ANESTHETICS AND MANAGEMENT OF THE RESPIRATORY EFFECTS OF POTENT OPIOIDS. AN OPIOID ANTAGONIST, RESUSCITATIVE AND INTUBATION EQUIPMENT AND OXYGEN SHOULD BE READILY AVAILABLE. As with other potent narcotics, the respiratory depressant effect of fentanyl may persist longer than the measured analgesic effect.
It is recommended that narcotics, when required, should be used in reduced doses initially, as low as 1/4 to 1/3 of those usually recommended. Fentra (Fentanyl Citrate) Injection may cause muscle rigidity, particularly involving the muscles of respiration.This effect is related to the dose and speed of injection.
Fentanyl may also produce other signs and symptoms characteristic of narcotic analgesics including euphoria, miosis, bradycardia and bronchoconstriction.
Head Injuries and Increased Intracranial Pressure
Fentanyl should be used with caution in patients who may be particularly susceptible to respiratory depression, such as comatose patients who may have a head injury or brain tumor.

PRECAUTIONS
General
The initial dose of fentanyl citrate should be appropriately reduced in elderly and debilitated patients. The effect of the initial dose should be considered in determining incremental doses. Nitrous oxide has been reported to produce cardiovascular depression when given with higher doses of fentanyl. When fentanyl is used to supplement anesthesia, the anesthetist should be familiar with the physiological alterations involved, and be prepared to manage them in the patients selected for these forms of anesthesia. When fentanyl is used with a tranquilizer such as droperidol, hypotension can occur. If it occurs, the possibility of hypovolemia should also be considered and managed with appropriate parenteral fluid therapy. Care should be exercised in moving and positioning of patients because of the possibility of orthostatic hypotension. Elevated blood pressure, with and without pre-existing hypertension, has been reported following administration of fentanyl citrate due to unexplained alterations in sympathetic activity following large doses. Vital signs should be monitored routinely. Respiratory depression caused by opioid analgesics can be reversed by opioid antagonists such as naloxone and appropriate surveillance should be maintained. Intraoperative hyperventilation may further alter postoperative response to CO_2.
Impaired Respiration
Fentanyl Citrate should be used with caution in patients with chronic obstructive pulmonary disease, patients with decreased respiratory reserve, and others with potentially compromised respiration.
Impaired Hepatic or Renal Function
Fentanyl citrate should be administered with caution to patients with liver and kidney dysfunction because of the importance of these organs in the metabolism and excretion of drugs.
Cardiovascular Effects
Fentanyl Citrate may produce bradycardia, which may be treated with atropine. Fentanyl should be used with caution in patients with cardiac bradyarrhythmias.

DRUG INTERACTIONS
Other CNS depressant drugs (e.g., barbiturates, tranquilizers, narcotics and general anesthetics) will have additive or potentiating effects with fentanyl. When patients have received such drugs, the dose of fentanyl required will be less than usual. Following the administration of fentanyl citrate, the dose of other CNS depressant drugs should be reduced.

USE IN SPECIAL SITUATIONS:
Carcinogenesis, Mutagenesis, Impairment of Fertility
No carcinogenicity or mutagenicity studies have been conducted with fentanyl citrate.
Pregnancy
Pregnancy Category C there are no adequate and well-controlled studies in pregnant women. Fentanyl should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Labor and Delivery
There are insufficient data to support the use of fentanyl in labor and delivery. Therefore, such use is not recommended.
Nursing Mothers
It is not known whether this drug is excreted in human milk, caution should be exercised when fentanyl citrate is administered to a nursing woman.
Pediatric Use
The safety and efficacy of fentanyl citrate in pediatric patients under two years of age has not been established.

SIDE EFFECTS
As with other narcotic analgesics, the most common serious adverse reactions reported to occur with fentanyl are respiratory depression, apnea, rigidity and bradycardia; if these remain untreated, respiratory arrest, circulatory depression or cardiac arrest could occur. Other adverse reactions that have been reported are hypertension, hypotension, dizziness, blurred vision, nausea, emesis, laryngospasm and diaphoresis. It has been reported that secondary rebound respiratory depression may occasionally occur postoperatively. Patients should be monitored for this possibility and appropriate countermeasures taken as necessary. When a tranquilizer such as droperidol is used with fentanyl citrate, the following adverse reactions can occur: chills and/or shivering, restlessness and postoperative hallucinatory episodes (sometimes associated with transient periods of mental depression); extrapyramidal symptoms (dystonia, akathisia and oculogyric crisis) have been observed up to 24 hours postoperatively.

DRUG ABUSE AND DEPENDENCE
Fentanyl Citrate Injection is a Schedule II controlled drug substance that can produce drug dependence of the morphine type and, therefore, has the potential for being abused.

OVERDOSAGE
Manifestations
The intravenous LD 50 of fentanyl is 3mg/kg in rats, 1mg/kg in cats, 14 mg/kg in dogs and 0.03 mg/kg in monkeys.
Treatment
In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be assisted or controlled as indicated. A patent airway must be maintained; an oropharyngeal airway or endotracheal tube might be indicated. The patient should be carefully observed for 24 hours; body warmth and adequate fluid intake should be maintained. If hypotension occurs and is severe or persists, the possibility of hypovolemia should be considered and managed with appropriate parenteral fluid therapy. A specific narcotic antagonist such as naloxone should be available for use as indicated to manage respiratory depression.

STORAGE:
Store at temperature 15 ^{o}C to 30 ^{o}C away from light.

PRESENTATIONS:
Fentra 2ml Injection:
Fentra (Fentanyl citrate) is available in box of 2ml single ampoule
Fentra 5ml Injection:
Fentra (Fentanyl citrate) is available in box of 10x5ml ampoule.

خوراک اور طریقہ استعمال:

بڑوں میں: فینٹرا انجکشن کی عمومی خوراک ڈاکٹر مریض کو دیکھتے ہوتے طے کرے گا۔

پری میڈیکیشن: 50 سے 100 مائکروگرام (0.05 سے 0.1 ملی گرام) انٹرامسکلر 1/2 سے ایک گھنٹے سرجری سے قبل دی جاتی ہے۔

جنرل اینستھیزیا: 50 سے 100 مائکروگرام (0.05-0.1 ملی گرام) کو آکسیجن اور مسل ریلیکسنٹ کے ساتھ دینی چاہیے۔ زیادہ سے زیادہ 15mg/kg خوراک دی جاسکتی ہے۔

آپریشن کے بعد کی خوراک: 0.05 سے 0.1 ملی گرام انٹرامسکلر یا پھر وریدی راستہ سے درد کو کنٹرول کرنے کے لئے دی جاتی ہے۔

بچوں میں: دو سے بارہ سال کی عمر تک 2 سے 3 مائکروگرام/کلوگرام خوراک دینی چاہیے۔

اسٹوریج: 15 سے 30 ڈگری سینٹی گریڈ پر روشنی سے بچا کر رکھیں

brookes
Manufactured by:
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ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification