

# Fentanyl®

Fentanyl Citrate BP

### Presentation

Fentanyl® IV Injection: Each 2 ml injection contains Fentanyl Citrate BP equivalent to 100 mcg Fentanyl.

### Description

Fentanyl citrate is a potent narcotic analgesic. Each milliliter of solution contains fentanyl (as the citrate) 50 mcg. Fentanyl citrate injection is a sterile, nonpyrogenic, preservative free aqueous solution for intravenous or intramuscular injection.

### Mechanism of Action

Fentanyl® binds to the opioid mu-receptors throughout the body, producing many different effects. Some of these effects, such as pain relief, are desirable; other effects, such as slowing down the digestive tract, are undesirable and lead to side effects such as constipation.

### Indication

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 administration with a neuroleptic such as droperidol injection 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 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

50 mcg = 0.05 mg = 1 mL

Dosage should be individualized. Some of the factors to be considered in determining the dose are age, body weight, physical status, 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.

### Adult Dose

#### • Premedication

Premedication (to be appropriately modified in the elderly, debilitated and those who have received other depressant drugs)—50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly 30 to 60 minutes prior to surgery.

#### • Adjunct to Regional Anesthesia

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) may be administered intramuscularly or slowly intravenously, over one to two minutes, when additional analgesia is required.

#### • Adjunct to General Anesthesia

*Total low dose:* 2mcg/kg in small doses for minor, painful surgical procedures and post-operative pain relief.

Maintenance low dose: 2mcg/kg. Infrequently needed in minor procedures

*Total moderate dose:* 2 to 20mcg/kg. In addition to adequate analgesia, some abolition of the stress response should occur. Respiratory depression necessitates artificial ventilation and careful observation of postoperative ventilation.

Maintenance low dose: 2 to 20mcg/kg. 25 to 100mcg may be administered intravenously or intramuscularly when movement and/or changes in vital signs indicate surgical stress or lightening of analgesia.

*Total high dose:* 20 to 50mcg/kg. For “stress free” anesthesia. Use during open heart surgery and complicated neurosurgical and orthopedic procedures where surgery is prolonged and the stress response is detrimental. Inject with nitrous oxide/oxygen to attenuate the stress response. Postoperative ventilation and observation are required.

Maintenance low dose: 20 to 50mcg/kg. Maintenance dosage (ranging from 25mcg to half the initial loading dose) will be dictated by the changes in vital signs which indicate surgical stress and lightening of analgesia. However, the additional dosage selected must be individualized especially if the anticipated remaining operative time is short.

#### • Postoperatively (recovery room)

50 to 100 mcg (0.05 to 0.1 mg) (1 to 2 mL) 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.

### ADVERSE REACTIONS

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. When they occur, extrapyramidal symptoms can usually be controlled with anti-parkinson agents. Postoperative drowsiness is also frequently reported following the use of droperidol.

### 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.

### 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.

### PRECAUTIONS

#### Impaired Respiration

Fentanyl should be used with caution in patients with chronic obstructive pulmonary disease, patients with decreased respiratory reserve, and others with potentially compromised respiration. In such patients, narcotics may additionally decrease respiratory drive and increase airway resistance. During anesthesia, this can be managed by assisted or controlled 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 may produce bradycardia, which may be treated with atropine. Fentanyl should be used with caution in patients with cardiac bradyarrhythmias.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or mutagenicity studies have been conducted with fentanyl citrate. Reproduction studies in rats revealed a significant decrease in the pregnancy rate of all experimental groups. This decrease was most pronounced in the high dosed group (1.25 mg/kg—12.5X human dose) in which one of twenty animals became pregnant.

### Pregnancy

#### Teratogenic Effects

#### Pregnancy Category C

Fentanyl citrate has been shown to impair fertility and to have an embryocidal effect in rats when given in doses 0.3 times the upper human dose for a period of 12 days. No evidence of teratogenic effects have been observed after administration of fentanyl citrate to rats. 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

Since many drugs are 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.

### Overdosage

The manifestations of fentanyl overdosage are an extension of its pharmacologic actions.

### Commercial pack

**Fentanyl® IV Injection:** Each box contains 1x5 ampoules. Each ampoule contains Fentanyl 100mcg/2ml

 Manufactured by:  
**RENATA LIMITED**  
Dhaka, Bangladesh  
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