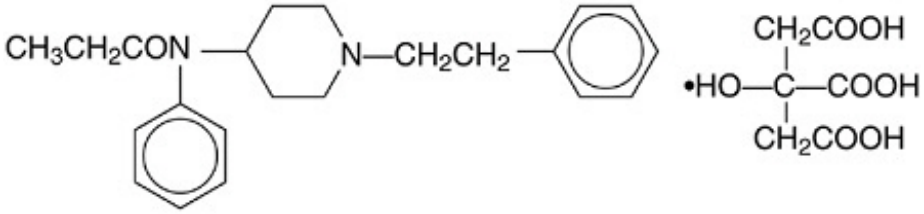
FENTANYL CITRATE- fentanyl citrate injection, solution
Hospira, Inc.

Fentanyl Citrate

Injection, USP Rx only

DESCRIPTION

Fentanyl Citrate Injection, USP is a potent opioid agonist. Each milliliter of solution contains fentanyl (as the citrate) 50 mcg (0.05 mg), adjusted to pH 4.0 to 7.5 with sodium hydroxide. Fentanyl citrate is chemically identified as *N*-(1-Phenethyl-4-piperidyl) propionanilide citrate (1:1) with a molecular weight of 528.61. The structural formula of fentanyl citrate is:



Fentanyl Citrate Injection, USP is a sterile, nonpyrogenic, preservative free aqueous solution for intravenous or intramuscular injection.

CLINICAL PHARMACOLOGY

Fentanyl citrate is a potent opioid agonist. 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. Alterations in respiratory rate and alveolar ventilation, associated with opioid analgesics, may last longer than the analgesic effect. As the dose of fentanyl is increased, the decrease in pulmonary exchange becomes greater. Large doses may produce apnea. Fentanyl appears to have less emetic activity than either morphine or meperidine. Histamine assays and skin wheal testing in man indicate that clinically significant histamine release rarely occurs with fentanyl. Recent assays in man show no clinically significant histamine release in dosages up to 50 mcg/kg (0.05 mg/kg) (1 mL/kg). Fentanyl 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 1.7 minutes, redistribution of 13 minutes, and a terminal elimination half-life of 219 minutes. The volume of distribution for fentanyl is 4 L/kg.

Fentanyl plasma protein binding capacity decreases with increasing ionization of the drug. Alterations in pH may affect its distribution between plasma and the central nervous system. It accumulates in skeletal muscle and fat, and 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; however, the maximal analgesic and respiratory depressant effect may not be noted for several minutes. The usual duration of action of the analgesic effect is 30 to 60 minutes after a single intravenous dose of up to

100 mcg (0.1 mg) (2 mL). 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 opioid analgesics, the duration of the respiratory depressant effect of fentanyl may be longer than the analgesic effect. The following observations have been reported concerning altered respiratory response to CO_2 stimulation following administration of fentanyl citrate to man.

1. DIMINISHED SENSITIVITY TO CO_2 STIMULATION MAY PERSIST LONGER THAN DEPRESSION OF RESPIRATORY RATE. (Altered sensitivity to CO_2 stimulation has been demonstrated for up to four hours following a single dose of 600 mcg (0.6 mg) (12 mL) fentanyl to healthy volunteers.) Fentanyl frequently slows the respiratory rate, duration, and degree of respiratory depression being dose related.
2. The peak respiratory depressant effect of a single intravenous dose of fentanyl citrate is noted 5 to 15 minutes following injection. See also **WARNINGS** and **PRECAUTIONS** concerning respiratory depression.

INDICATIONS AND USAGE

Fentanyl Citrate Injection, USP 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 an opioid analgesic supplement in general or regional anesthesia.
- for administration with a neuroleptic 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.

CONTRAINDICATION

Fentanyl Citrate Injection, USP is contraindicated in patients with known intolerance to the drug or other opioid agonists.

WARNINGS

FENTANYL CITRATE 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.

See also discussion of opioid antagonists in **PRECAUTIONS** and **OVERDOSAGE**.

If fentanyl is administered with a tranquilizer, the user should become familiar with the special properties of each drug, particularly the widely differing duration of action. In addition, when such a combination is used, fluids and other countermeasures to manage hypotension should be available.

As with other potent opioids, the respiratory depressant effect of fentanyl may persist longer than the measured analgesic effect. The total dose of all opioid agonists administered should be considered by the practitioner before ordering opioid analgesics during recovery from anesthesia. It is recommended that opioids, when required, should be used in reduced doses initially, as low as 1/4 to 1/3 those usually recommended.

Fentanyl may cause muscle rigidity, particularly involving the muscles of respiration. This rigidity has been reported to occur or recur infrequently in the extended postoperative period usually following

high dose administration. In addition, skeletal muscle movements of various groups in the extremities, neck, and external eye have been reported during induction of anesthesia with fentanyl; these reported movements have, on rare occasions, been strong enough to pose patient management problems. This effect is related to the dose and speed of injection and its incidence can be reduced by: 1) administration of up to 1/4 of the full paralyzing dose of a nondepolarizing neuromuscular blocking agent just prior to administration of fentanyl citrate; 2) administration of a full paralyzing dose of a neuromuscular blocking agent following loss of eyelash reflex when fentanyl is used in anesthetic doses titrated by slow intravenous infusion; or, 3) simultaneous administration of fentanyl citrate and a full paralyzing dose of a neuromuscular blocking agent when fentanyl citrate is used in rapidly administered anesthetic dosages. The neuromuscular blocking agent used should be compatible with the patient's cardiovascular status.

Adequate facilities should be available for postoperative monitoring and ventilation of patients administered anesthetic doses of fentanyl. Where moderate or high doses are used (above 10 mcg/kg), there must be adequate facilities for postoperative observation, and ventilation if necessary, of patients who have received fentanyl. It is essential that these facilities be fully equipped to handle all degrees of respiratory depression.

Fentanyl may also produce other signs and symptoms characteristic of opioid agonists including euphoria, miosis, bradycardia, and bronchoconstriction.

Severe and unpredictable potentiation by MAO inhibitors has been reported for other opioid agonists. Although this has not been reported for fentanyl, there are insufficient data to establish that this does not occur with fentanyl. Therefore, when fentanyl is administered to patients who have received MAO inhibitors within 14 days, appropriate monitoring and ready availability of vasodilators and beta-blockers for the treatment of hypertension is indicated.

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. In addition, fentanyl may obscure the clinical course of patients with head injury.

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.

Certain forms of conduction anesthesia, such as spinal anesthesia and some peridural anesthetics, can alter respiration by blocking intercostal nerves. Through other mechanisms (see **CLINICAL PHARMACOLOGY**) fentanyl can also alter respiration. Therefore, when fentanyl is used to supplement these forms of 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 a tranquilizer is used with fentanyl, pulmonary arterial pressure may be decreased. This fact should be considered by those who conduct diagnostic and surgical procedures where interpretation of pulmonary arterial pressure measurements might determine final management of the patient. When high dose or anesthetic dosages of fentanyl are employed, even relatively small dosages of diazepam may cause cardiovascular depression.

When fentanyl is used with a tranquilizer, hypotension can occur. If it occurs, the possibility of hypovolemia should also be considered and managed with appropriate parenteral fluid therapy. Repositioning the patient to improve venous return to the heart should be considered when operative conditions permit. Care should be exercised in moving and repositioning of patients because of the

possibility of orthostatic hypotension. If volume expansion with fluids plus other countermeasures do not correct hypotension, the administration of pressor agents other than epinephrine should be considered. Epinephrine may paradoxically decrease the blood pressure in patients treated with a neuroleptic that blocks alpha adrenergic activity.

Elevated blood pressure, with and without preexisting hypertension, has been reported following administration of fentanyl citrate combined with a neuroleptic. This might be due to unexplained alterations in sympathetic activity following large doses; however, it is also frequently attributed to anesthetic and surgical stimulation during light anesthesia.

When fentanyl is used with a neuroleptic and the EEG is used for postoperative monitoring, it may be found that the EEG pattern returns to normal slowly.

Many neuroleptic agents have been associated with QT prolongation, torsades de pointes, and cardiac arrest. Neuroleptic agents should be administered with extreme caution in the presence of risk factors for development of prolonged QT syndrome and torsades de pointes, such as: 1) clinically significant bradycardia (less than 50 bpm), 2) any clinically significant cardiac disease, including baseline prolonged QT interval, 3) treatment with Class 1 and Class III antiarrhythmics, 4) treatment with monoamine oxidase inhibitors (MAOI's), 5) concomitant treatment with other drug products known to prolong the QT interval and 6) electrolyte imbalance, in particular hypokalemia and hypomagnesemia, or concomitant treatment with drugs (e.g. diuretics) that may cause electrolyte imbalance.

ECG monitoring is indicated when a neuroleptic agent is used in conjunction with fentanyl as an anesthetic premedication, for the induction of anesthesia, or as an adjunct in the maintenance of general or regional anesthesia.

Vital signs should be monitored routinely.

Respiratory depression caused by opioid analgesics can be reversed by opioid antagonists such as naloxone. Because the duration of respiratory depression produced by fentanyl may last longer than the duration of the opioid antagonist action, appropriate surveillance should be maintained. As with all potent opioids, profound analgesia is accompanied by respiratory depression and diminished sensitivity to CO_2 stimulation which may persist into or recur in the postoperative period. Respiratory depression secondary to chest wall rigidity has been reported in the postoperative period. Intraoperative hyperventilation may further alter postoperative response to CO_2. Appropriate postoperative monitoring should be employed to ensure that adequate spontaneous breathing is established and maintained in the absence of stimulation prior to discharging the patient from the recovery area.

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, opioids 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.

Drug Interactions: Other CNS depressant drugs (e.g., barbiturates, tranquilizers, opioids, 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.

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 dose group (1.25 mg/kg-12.5X human dose) in which one of twenty animals became pregnant.

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: It is not known whether this drug is excreted in human milk. Because 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 children under two years of age has not been established.

Rare cases of unexplained clinically significant methemoglobinemia have been reported in premature neonates undergoing emergency anesthesia and surgery which included the combined use of fentanyl, pancuronium, and atropine. A direct cause and effect relationship between the combined use of these drugs and the reported cases of methemoglobinemia has not been established.

ADVERSE REACTIONS

As with opioid agonists, 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, diaphoresis, pruritus, urticarial, laryngospasm, and anaphylaxis.

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 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 antiparkinson agents. Postoperative drowsiness is also frequently reported following the use of neuroleptics with fentanyl citrate.

Cases of cardiac dysrhythmias, cardiac arrest, and death have been reported following the use of fentanyl citrate with a neuroleptic agent.

DRUG ABUSE AND DEPENDENCE

Fentanyl Citrate Injection, USP 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 manifestations of fentanyl overdosage are an extension of its pharmacologic actions (see **CLINICAL PHARMACOLOGY**) as with other opioid analgesics. The intravenous LD_{50} of fentanyl is 3 mg/kg in rats, 1 mg/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. If depressed respiration is associated with muscular

rigidity, an intravenous neuromuscular blocking agent might be required to facilitate assisted or controlled respiration. 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 opioid antagonist such as naloxone should be available for use as indicated to manage respiratory depression. This does not preclude the use of more immediate countermeasures. The duration of respiratory depression following overdosage of fentanyl may be longer than the duration of the opioid antagonist action. Consult the package insert of the individual opioid antagonists for details about use.

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 (see **PRECAUTIONS**).

Vital signs should be monitored routinely.

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

II. **Adjunct to General Anesthesia** — See Dosage Range Chart

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

IV. **Postoperatively (recovery room)** — 50 mcg to 100 mcg (0.05 mg to 0.1 mg) (1 mL 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 mcg/kg to 3 mcg/kg is recommended.

DOSAGE RANGE CHART

TOTAL DOSAGE (expressed as fentanyl base)		
Low Dose -	**Moderate Dose -**	**High 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. In addition to the analgesia during surgery, Fentanyl may also provide some pain relief in the immediate postoperative period.	2-20 mcg/kg (0.002–0.02 mg/kg) (0.04–0.4 mL/kg) Where surgery becomes more major, a larger dose is required. With this dose, in addition to adequate analgesia, one would expect to see some abolition of the stress response. However, respiratory depression will be such that artificial ventilation during anesthesia is necessary and careful observation of	20-50 mcg/kg (0.02-0.05 mg/kg) (0.4–1 mL/kg) During open heart surgery and certain more complicated neurosurgical and orthopedic procedures where surgery is more prolonged, and in the opinion of the anesthesiologist, the stress response to surgery would be detrimental to the well being of the patient, dosages of 20–50 mcg/kg (0.02-0.05 mg/kg) (0.4–1 mL/kg) of fentanyl with nitrous oxide/oxygen have been shown to attenuate the stress response as defined by increased levels of circulating growth hormone, catecholamine, ADH, and prolactin. When dosages in this range have been used during surgery,

	ventilation postoperatively is essential.	postoperative ventilation and observation are essential due to extended postoperative respiratory depression. The main objective of this technique would be to produce "stress-free" anesthesia.

DOSAGE RANGE CHART

MAINTENANCE DOSAGE (expressed as fentanyl base)		
Low Dose -	**Moderate Dose -**	**High Dose -**
2 mcg/kg (0.002 mg/kg) (0.04 mL/kg) Additional dosages of fentanyl are infrequently needed in these minor procedures.	2-20 mcg/kg (0.002-0.02 mg/kg) (0.04–0.4 mL/kg) 25-100 mcg (0.025 to 0.1 mg) (0.5 to 2 mL) may be administered intravenously or intramuscularly when movement and/or changes in vital signs indicate surgical stress or lightening of analgesia.	20-50 mcg/kg (0.02-0.05 mg/kg) (0.4–1 mL/kg) Maintenance dosage (ranging from 25 mcg (0.025 mg)(0.5 mL) to one half the initial loading dose) will be dictated by the changes in vital signs which indicate stress and lightening of analgesia. However, the additional dosage selected must be individualized especially if the anticipated remaining operative time is short.

As a General Anesthetic:

When attenuation of the responses to surgical stress is especially important, doses of 50 mcg/kg to 100 mcg/kg (0.05 mg/kg to 0.1 mg/kg) (1 mL/kg 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 150 mcg/kg (0.15 mg/kg) (3 mL/kg) may be necessary to produce this anesthetic effect. It has been used for open heart surgery and certain other major surgical procedures in patients for whom protection of the myocardium from excess oxygen demand is particularly indicated, and for certain complicated neurological and orthopedic procedures.

As noted above, it is essential that qualified personnel and adequate facilities be available for the management of respiratory depression.

See **WARNINGS** and **PRECAUTIONS** for use of fentanyl with other CNS depressants, and in patients with altered response.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Fentanyl citrate injection, USP, equivalent to 50 mcg 5fentanyl per mL is supplied as:

Unit of Sale	**Concentration (per total volume)**	**Each**
NDC 0409-1276-32 Carton of 10	100 mcg/ 2mL (50 mcg/mL)	NDC 0409-1276-03 2 mL fill in 2.5 mL Carpuject™ Single-use cartridge with Luer Lock for the Carpuject™ Syringe System

Carpuject™ Single-use cartridges with Luer Lock are packaged in a Slim-Pak™ tamper detection package. Note that a needle is not included.

Instructions for Use of the Syringe Systems

Instructions for using the Carpuject™ Syringe are available with the reusable Carpuject™ Holder, List 2049-02.

Carpuject™ Single-use cartridges are to be used ONLY with Carpuject™ Holders, List 2049-02.

PROTECT FROM LIGHT. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

LAB-0829-1.0

9/2016

Hospira, Inc., Lake Forest, IL 60045 USA

PRINCIPAL DISPLAY PANEL - 2 mL Cartridge Label

2 mL Single-use **Carpuject™**
Sterile Cartridge Unit with Luer Lock

NDC 0409-1276-03

Fentanyl Citrate Injection, USP
100 mcg Fentanyl / 2 mL
(50 mcg/mL)
CII

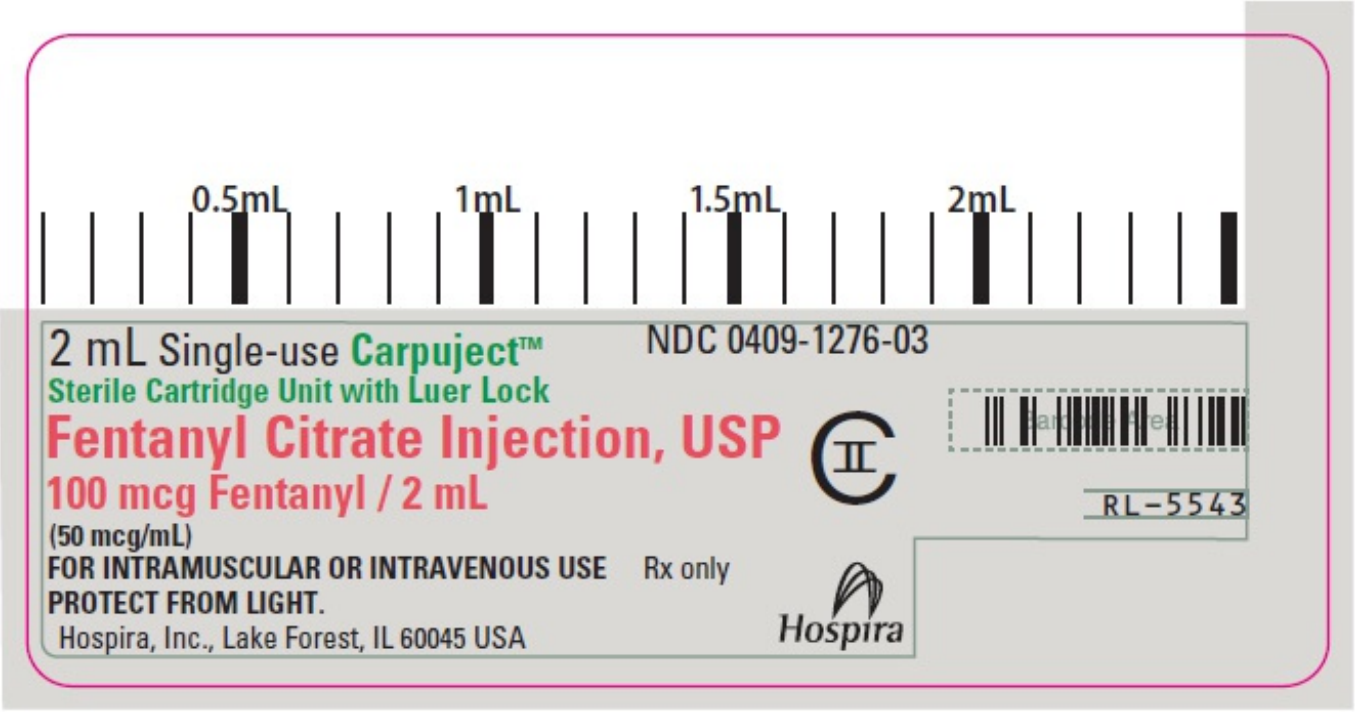
FOR INTRAMUSCULAR OR INTRAVENOUS USE
PROTECT FROM LIGHT.

Rx only

Hospira, Inc., Lake Forest, IL 50045 USA

Hospira

RL-5543



PRINCIPAL DISPLAY PANEL - 10 Cartridge Carton

2 mL Single-Use
NDC 0409-1276-32
Rx only

10 Carpuject™
Sterile Cartridge Units
with Luer Lock

Needle not included

SLIM-PAK™
Tamper Detection Package

Fentanyl
Citrate
Injection,
USP
100 mcg Fentanyl / 2 mL
(50 mcg/mL)
CII

For Intravenous or
Intramuscular Use

Carpuject Cartridges are to be used
ONLY with Carpuject Holders.

Hospira

THIS END UP

2 mL Single-use

10 Carpuject™ Sterile Cartridge Units with Luer Lock

Fentanyl Citrate Injection, USP

100 mcg Fentanyl / 2 mL

(50 mcg/mL)

Hospira

2 mL Single-Use NDC 0409-1276-32

Rx only

10 Carpuject™

Sterile Cartridge Units with Luer Lock

Needle not included

SLIM-PAK™

Tamper Detection Package

Fentanyl Citrate Injection, USP

100 mcg Fentanyl / 2 mL

(50 mcg/mL)

For Intravenous or Intramuscular Use

Carpuject Cartridges are to be used ONLY with Carpuject Holders.

Hospira

(01)10304091276328

2 mL Single-use

10 Carpuject™ Sterile Cartridge Units with Luer Lock

Fentanyl Citrate Injection, USP

100 mcg Fentanyl / 2 mL

(50 mcg/mL)

Hospira

0 9 8 7 6 5 4 3 2 1

2 mL Single-use

10 Carpuject™ Sterile Cartridge Units with Luer Lock

Needle not included

Fentanyl Citrate Injection, USP

100 mcg Fentanyl / 2 mL

(50 mcg/mL)

For Intravenous or Intramuscular Use

Carpuject Cartridges are to be used ONLY with Carpuject Holders.

Sterile Aqueous Injection

Each mL of this sterile solution contains fentanyl (as the citrate) 50 mcg, adjusted to pH 4.0-7.5 with sodium hydroxide.

Protect CARPUJECT from light.

Retain in carton until time of use.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

For usual dosage and route of administration, see package insert.

Hospira, Inc.
Lake Forest, IL 60045 USA

Hospira

CA-4232

Variable Data Area

1/16 Ink Free

TO OPEN LIFT FLAP
TO CLOSE INSERT FLAP INTO CARTON

2 mL Single-use 10 Carpuject™ Sterile Cartridge Units with Luer Lock

Fentanyl Citrate Injection, USP

100 mcg Fentanyl / 2 mL

(50 mcg/mL)

Hospira

FENTANYL CITRATE

fentanyl citrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-1276
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FENTANYL CITRATE (UNII: MUN5LYG46H) (FENTANYL - UNII:UF599785JZ)	FENTANYL	50 ug in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0409-1276-32	10 in 1 CARTON	07/20/2005	
1	NDC:0409-1276-03	2 mL in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072786	07/20/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		030606222	ANALYSIS(0409-1276) , LABEL(0409-1276) , MANUFACTURE(0409-1276) , PACK(0409-1276)

Revised: 9/2016 Hospira, Inc.