



Fentanyl

Citrate Injection, USP

50 mcg per 1 mL and 100 mcg per 2 mL
Simplist® ready-to-administer prefilled syringes
available from Fresenius Kabi

Manufacturer prepared

24-month shelf life

Preservative free

Tamper-evident packaging

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF FENTANYL CITRATE INJECTION

Addiction, Abuse, and Misuse
Because the use of Fentanyl Citrate Injection exposes patients and other users to the risks of opioid addiction, abuse and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of Fentanyl Citrate Injection, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of Fentanyl Citrate Injection are essential.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of Fentanyl Citrate Injection and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Cytochrome P450 3A4 Interaction

The concomitant use of Fentanyl Citrate Injection with all cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in fentanyl plasma concentration. Monitor patients receiving Fentanyl Citrate Injection and any CYP3A4 inhibitor or inducer.

CONTRAINDICATIONS

Fentanyl Citrate Injection is contraindicated in patients with a hypersensitivity to fentanyl.

WARNINGS AND PRECAUTIONS

- **Risks of Skeletal Muscle Rigidity and Skeletal Muscle Movement:** Manage with neuromuscular blocking agent. See full prescribing information for more detail on managing these risks.
- **Severe Cardiovascular Depression:** Monitor during dosage initiation and titration.
- **Opioid-Induced Hyperalgesia and Allodynia:** Opioid-Induced Hyperalgesia (OIH) occurs when an opioid analgesic paradoxically causes an increase in pain, or an increase in sensitivity to pain. If OIH is suspected, carefully consider appropriately decreasing the dose of the current opioid analgesic, or opioid rotation.
- **Serotonin Syndrome:** Potentially life-threatening condition could result from concomitant serotonergic

drug administration. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected.

- **Adrenal Insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.
- **Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, or Head Injury:** Monitor for sedation and respiratory depression.

ADVERSE REACTIONS

The most common serious adverse reactions were respiratory depression, apnea, rigidity, and bradycardia.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 option 5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- **Concomitant Use of CNS Depressants:** May decrease pulmonary arterial pressure and may cause hypotension. See FPI for management instructions. For post-operative pain, start with the lowest effective dosage and monitor for potentiation of CNS depressant effects.
- **Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics:** Avoid use with Fentanyl Citrate Injection because they may reduce the analgesic effect of Fentanyl Citrate Injection or precipitate withdrawal symptoms.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** Infants exposed to Fentanyl Citrate Injection through breast milk should be monitored for excess sedation and respiratory depression.

- **Geriatric Patients:** Titrate slowly and monitor for CNS and respiratory depression.

INDICATION AND USAGE

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.
- use as an opioid analgesic supplement in general or regional anesthesia.
- 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.
- 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.



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. Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available.

This Important Safety Information does not include all the information needed to use Fentanyl Citrate Injection, USP safely and effectively. Please see full prescribing information, including BOXED WARNING, for Fentanyl Citrate Injection, USP at www.simplist-us.com.

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Strength	50 mcg per 1 mL	100 mcg per 2 mL
Concentration	50 mcg per 1 mL	50 mcg per 1 mL
Fill volume	1 mL	2 mL
Unit of sale NDC	63323-808-11	63323-810-20
Unit of sale bar code	 N(01)30363323808113	 (01)30363323810208
Pack size	10 per Carton (Bundles of 5)	20 per Carton
Secondary packaging	MicroVault®	Blister
Secondary packaging dimensions	3.625" x .75"	5.748" x 1.063"
Carton dimensions	3.125" x 2.625" x 4.375"	6.25" x 2.402" x 6.575"
Wholesale numbers		
Cardinal	5699947	5853759
Cencora	10253772	10281197
McKesson	1598895	2829000
Morris & Dickson	971754	292276

**To place an order, contact your Sales Representative or call Customer Service at
1.888.386.1300 | www.simplist-us.com**