

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

Fentanyl Citrate Injection, USP

INDICATIONS AND USAGE

Fentanyl Citrate Injection, for intravenous or intramuscular use, 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.

IMPORTANT SAFETY INFORMATION:

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- Fentanyl Citrate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of fentanyl.
- 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 for

use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

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

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.

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.

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.

Concomitant Use of CNS Depressants: May decrease pulmonary arterial pressure and may cause hypotension. See full prescribing information 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.

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.

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

Fentanyl

Citrate Injection, USP



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		
AmerisourceBergen	10253772	10281197
Cardinal	5699947	5853759
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**