FENTANYL CITRATE Injection, USP
50 mcg/mL 2 mL fliptop vial

DESCRIPTION
Fentanyl citrate is a synthetic opioid analgesic. Its chemical name is 4′-(1-piperidinylmethyl) morphinan-3′-yl acetate. It is related structurally to codeine, morphine, and other opioid analgesics. The chemical formula is C₂₉H₃₅NO₅. Its molecular weight is 473.59. It is a white or almost white, odorless, bitter tasteless powder. It is sparingly soluble in water. It is classified as a controlled substance under the U.S. Controlled Substances Act of 1970.

CLINICAL PHARMACOLOGY
Fentanyl is a highly potent, short acting synthetic opioid analgesic. It produces effects similar to those of morphine in analgesic doses. However, it is 50 to 100 times more potent than morphine in most clinical situations. Fentanyl is rapidly and completely absorbed after oral administration and produces analgesia within five minutes. The drug is extensively metabolized by the liver, with only about 1% of an oral dose appearing in the urine as unchanged drug. Approximately 80% of the drug is excreted in the urine as metabolic products. The elimination half-life of fentanyl is 4 to 6 hours. Fentanyl is highly lipid soluble and crosses the blood-brain barrier readily.

CONTRAINDICATIONS
Fentanyl is contraindicated in patients with a known history of sensitivity to the drug. It is also contraindicated in patients with a known history of asthma or other airway obstruction. Fentanyl is also contraindicated in patients with a known history of respiratory depression, including those with a history of chronic obstructive pulmonary disease (COPD) or other chronic lung disease. Fentanyl is also contraindicated in patients with a known history of severe hypertension or a known history of severe heart disease.

WARNINGS
Fentanyl Citrate Injection, USP is intended for use in the hospital setting. It is not intended for use at home. Fentanyl Citrate Injection, USP is not intended for use in children.

PRECAUTIONS
Fentanyl Citrate Injection, USP should be used with caution in patients with a history of lung disease, heart disease, or other medical conditions that may affect the respiratory system. Patients with a history of drug abuse or alcoholism may be more sensitive to the effects of fentanyl.

ADVERSE REACTIONS
The most common adverse reactions associated with the use of fentanyl are respiratory depression, sedation, nausea, vomiting, constipation, and pruritus. Other rare adverse reactions include hypersensitivity reactions, respiratory arrest, and cardiovascular collapse.

DOSE AND ADMINISTRATION
Fentanyl Citrate Injection, USP is available in a single-dose glass vial. It is supplied in a concentration of 50 mcg/mL. The dose for intravenous administration should be individualized. The usual dose for intravenous administration is 1 to 3 mcg/kg, administered over 1 to 5 minutes. The dose for intramuscular administration is 5 to 10 mcg/kg, administered over 1 to 5 minutes.

OVERDOSAGE
Overdosage of fentanyl can result in respiratory depression, hypotension, and cardiovascular collapse. Treatment should be initiated with support of respiratory and circulatory systems. In general, supportive care is the most important aspect of treatment. If respiratory depression is present, respiratory support should be initiated. If hypotension is present, fluid replacement and vasoactive support should be initiated. If cardiovascular collapse is present, advanced cardiac life support should be initiated.

PROVIDER INFORMATION
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PATIENT INFORMATION
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