SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT

FENSTUD INJECTION 50 MCG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Fentanyl Citrate USP Equivalent to Fentanyl 50 mcg;
Water for Injection BP q.s.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fentanyl Citrate is a strong analgesic used preoperatively during surgery and in the immediate post operative period for its analgesic action.

1. Used as an analgesic and an adjunct to general anasthetics.
2. As an anesthetic for induction and maintenance of anesthesia.
3. As an adjunct to regional anesthesia.

4.2 Posology and Method of administration

1. Preoperative Medication
50 - 100µg of Fentanyl is administered IM 30 – 60 minutes prior to surgery.
2. As an adjunct to general anesthesia Fentanyl may be given in low dose, moderate dose or high dose regimen.
LOW DOSE
Used for minor but painful surgical procedures and IV dose of 2µg / kg is administered. Additional doses are usually not necessary.
MODERATE DOSE
Used in major surgical procedures an initial IV dose of 2 – 20 µg / kg is administered; additional doses of 25 – 100 µg may be given IV or IM as necessary.
HIGH DOSE
May be used during open heart surgery or certain complicated neurosurgical or orthopaedic procedures where surgery is more prolonged. An initial IV dose of 20 – 50 µg / kg may be given, additional doses ranging from 25 µg to one half of the initial dose may be administered as necessary.
3. As an adjunct to Regional anesthesia 50 – 100 µg of Fentanyl may be administered or by slow IV injection over 1 – 2 minutes when additional analgesia is required.
4. Post operative pain
For control of P.O. pain, restlessness, tachypnoea and emergence delirium 50 – 100 µg of the drug may be administered IM every 1 – 2 hours as needed.
5. Children : During induction and maintenance phases of general anesthesia in children 2 – 12 years of age of a Fentanyl dose of 1.7 – 3.3 µg / kg is recommended.

Dosage adjustment for the concomitantly administered drug may also be necessary.

4.3 Contraindications

1. Respiratory depression
2. Raised intracranial pressure
3. Hypovolaemia / Hypotension

4.4 Special warnings and precautions or use

1. Caution is advised in patients with myasthenia gravis; the effects of muscular rigidity on respiration may be particularly pronounced in these patients.
2. Fentanyl citrate appears to cause a lower incidence of nausea and vomiting than do other opiate agonists. Skeletal and thoracic muscle rigidity occur frequently especially following rapid IV administration of Fentanyl.
3. Muscular rigidity may be associated with reduced pulmonary compliance and / or apnoea, laryngospasm and bronchoconstriction and may be managed by use of assisted or controlled respiration or if necessary by IV administration of a neuromuscular blocking agent.
4. Fentanyl should be used with caution in patients with cardiac bradyarrythmias.
5. When Fentanyl is used in combination with other drugs such as droperidol the caution applicable to that drug should also be considered.
6. Use of Fentanyl is not recommended in patients who have received monoamine oxidase (MAO) inhibitors within 14 days.

4.5 Interaction with other medicinal products and other forms of Interaction

1. Ritonavir might prolong fentanyl induced respiratory depression. The plasma clearance of Fentanyl was decreased and the elimination half life and the area under plasma concentration time curve increased when given concomitantly with ritovir in a study in healthy subjects.
2. An additive sedative effect is to be expected when benzodiazepines are used with opoid analgesics in analgesic or anesthetic regimens but there are reports of severe respiratory depression with midazolam and Fentanyl.
3. The concurrent administration of propofol with other CNS depressants including those used in premedication may increase the sedative, anesthetic and cardiorespiratory depressant effects of Propofol.

4.6 Fertility, pregnancy, and lactation

Safe use of Fentanyl during pregnancy has not been established therefore the drug should not be administered to pregnant women unless the possible benefits outweigh the potential risks.

Effects on ability to use and drive machines

No information

4.8 Undesirable effects

Respiratory depression which occurs especially with high doses of Fentanyl responds to naloxone. Atropine may be used to block vagal effects of Fentanyl such as bradycardia. Unlike Morphine, Fentanyl is reported not to cause significant histamine release. Transient hypotension may follow intravenous administration. Muscle rigidity may occur and may require administration of neuromuscular blockers.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system.

4.9 Overdose

No significant information.

5. Pharmacological properties

5.1 Pharmacodynamics Properties

Fentanyl, a phenyl piperadine derivative is a potent opioid analgesic chemically related to pethidine and is primarily a μ opioid agonist.

5.2 Pharmacokinetic properties

After Parenteral administration, Fentanyl Citrate has a rapid onset and short duration of action. It is metabolized in the liver by N – dealkylation and hydroxylation. Metabolites and some unchanged drug are excreted mainly in the urine. The short duration of action is probably due to rapid redistribution into the tissues rather than metabolism and excretion.

An elimination half life of about 4 hours reflects slower release from tissue depots. About 80% has been reported to be bound to plasma proteins. Fentanyl appears in the cerebrospinal fluid. The onset of action following IV administration is rapid, peak analgesia occurs within several minutes and the duration of analgesia is 30 – 60 minutes after a single dose of upto 100 mcg. Following IM administration of Fentanyl Citrate, the onset of action occurs within about 7 – 15 minutes and the duration of action is 1 – 2 hours. Respiratory depressant effects may persist longer than analgesia. Residual effects of one dose of Fentanyl Citrate may potentiate the effects of subsequent doses. It has been suggested that redistribution is the main cause of the brief analgesic effect of Fentanyl.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

1. Citric acid
2. Water for injection

6.2 Incompatibilities
None

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store at the temperature not exceeding 30^0C. Protect from light. Do not freeze.

6.5 Nature and contents of container
2 ml and 10 ml, transparent chop off ampoule with Red band on neck, Ampoule Type:USP Type I

6.7 Special precautions for Disposal.
No special precautions

7. MANUFACTURING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESS
Manufacturer:
Rusan Pharma Ltd – Dehradhun
Khasra No.122mi,Central Hope Town, Behind Pharma City, Selaqui,
India

Marketing Authorisation Holder:
Rusan Pharma Ltd
58 / D, Govt. Industrial Estate, Charkop, Kandivali (W), 400067, Mumbai, India

8. MARKETING AUTHORIZATION NUMBER
H2022/CTD7776/14211

9. DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION
01/12/2022

10. DATE OF REVISION OF TEXT
01/12/2022