

Fentanyl Kalceks 0.05 mg/ml solution for injection

Fentanyl is a synthetic opioid with a µ-agonist pharmacological effect. Fentanyl is a potent opioid analgesic and can be used as an analgesic supplement in general anaesthesia or as an anaesthetic alone. A dose of 100 micrograms (2.0 ml) has a similar analgesic effect as 10 mg morphine. Fentanyl has a rapid onset of action. The maximum analgesic effect and the depressant effect on respiration take place within a few minutes. The mean duration of action of the analgesic effect is approximately 30 minutes after a single dose up to 100 micrograms. The depth of analgesia is dose dependent and can be adjusted to the pain level of the surgical procedure.

Approved:

Commercial production in USA, in 1968; Commercial production in Europe, in 1963.

Indications:

Fentanyl is a short acting opioid used:

- as an intravenous analgesic agent in surgical procedures;
- as an adjunct in the maintenance of general anaesthesia;
- in combination with a neuroleptic agent in the technique of neuroleptanalgesia;
- as a respiratory depressant/analgesic in patients requiring prolonged assisted ventilation;
- for induction of anaesthesia.

Method of administration

Fentanyl should be given only when in an environment where the airway can be controlled and by personnel who can control the airway.

The dose of fentanyl is adjusted individually according to age, body weight, physical status, pathological condition, co-medication and as well as type of surgical procedure and type of anaesthesia.

Fentanyl Advantages:

- Fentanyl is a synthetic opioid that is up to 80 to 100 times more potent than morphine. Fentanyl is highly lipid soluble, this allows fentanyl to cross the blood-cerebrospinal fluid barrier more rapidly and produce analgesic effects more quickly than morphine.
- Owing to faster redistribution and an elimination half-life of 4 hours, fentanyl also has a shorter duration of action (30 to 40 min) than morphine, making it ideal for the intubation requiring rapid induction and recovery from sedation and analgesia'.
- Adverse effects such as decreased gastrointestinal motility were also less commonly observed by using fentanyl².

Fentanyl Kalceks 0.05 mg/mL solution for injection available:

Type 1 colourless glass ampoules containing 2 ml of solution for injection. Ampoules are packed in a liner. Liners are packed in an outer carton.

Product shelf life - Unopened: 5 years

After opening the ampoule: Once opened, the product should be used immediately.

Special storage conditions:

Store in the original package in order to protect from light. Store below 30°C. Do not freeze.

Pack size:

10 ampoules of 2 ml

Special precautions for disposal and other handling:

For single use only. Discard any unused contents. The solution is to be visually inspected prior to use. Only clear solutions free from particles should be used.

Refer package insert for further information.

¹ Kandasamy, J. and Carlo, WA Assisted Ventilation of the Neonate (Sixth Edition). 34- PHarmacologic Therapies IV: Other Medications. **2017**, 366-379. e5. ² Yaster, M. The dose response of fentanyl in neonatal anesthesia. Anesthsiology 1987, 66:433-435.

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