Ultiva (remifentanil hydrochloride) - Drug Summary

Mylan Institutional LLC

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Ultiva
(remifentanil hydrochloride)

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

General Anesthesia

Induction of Anesthesia:
Usual: 0.5-1mcg/kg/min as continuous IV infusion w/ a hypnotic or volatile agent
If endotracheal intubation is to occur <8 min after start of infusion, an initial dose of 1mcg/kg may be administered over 30-60 sec

Maint of Anesthesia:
W/ Nitrous Oxide (66%):
Usual: 0.4mcg/kg/min continuous IV infusion
Range: 0.1-2mcg/kg/min
Supplemental IV Bolus: 1mcg/kg every 2-5 min

W/ Isoflurane (0.4-1.5):
Usual: 0.25mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.05-2mcg/kg/min
Supplemental IV Bolus Dose: 1mcg/kg every 2-5 min

W/ Propofol (100-200mcg/kg/min):
Usual: 0.25mcg/kg/min
Infusion Dose Range: 0.05-2mcg/kg/min
Supplemental IV Bolus Dose: 1mcg/kg every 2-5 min

At infusion rates >1mcg/kg/min, increases in the concomitant anesthetic agents should be considered to increase the depth of anesthesia

Monitored Anesthesia Care

Analgesic Component of Monitored Anesthesia Care:
Supplemental oxygen should be supplied

Single IV Dose: 0.5-1mcg/kg over 30-60 sec given 90 sec before the placement of the local or regional anesthetic block
Continuous IV Infusion:
Initial: 0.1mcg/kg/min beginning 5 min before placement of local or regional anesthetic block
Decrease infusion rate to 0.05mcg/kg/min following placement of the block
Thereafter, rate adjustments of 0.025mcg/kg/min at 5-min intervals may be used to balance patient's level of analgesia and respiratory rate

Postoperative Pain

For continuation as an analgesic into the immediate postoperative period
Initial: 0.1mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.025-0.2mcg/kg/min; may adjust infusion rate every 5 min in 0.025mcg/kg/min increments
Supplemental IV Bolus Dose: Not recommended

Coronary Artery Bypass Surgery

Induction of Anesthesia:

Usual: 1mcg/kg/min continuous IV infusion

Maint of Anesthesia:
Usual: 1mcg/kg/min
Infusion Dose Range: 0.125-4mcg/kg/min
Supplemental IV Bolus Dose: 0.5-1mcg/kg

Continuation as an analgesic into ICU:
Usual: 1mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.05-1mcg/kg/min

PEDIATRIC DOSAGE & INDICATIONS

General Anesthesia

Maint of Anesthesia:
An initial dose of 1mcg/kg may be administered over 30-60 sec

Birth-2 Months of Age:
W/ Nitrous Oxide (70%):
Usual: 0.4mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.4-1mcg/kg/min
Supplemental IV Bolus Dose: 1mcg/kg every 2-5 min

1-12 Years:
W/ Halothane (0.3-1.5):
Usual: 0.25mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.05-1.3mcg/kg/min
Supplemental IV Bolus Dose: 1mcg/kg every 2-5 min

W/ Sevoflurane (0.3-1.5):
Usual: 0.25mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.05-1.3mcg/kg/min
Supplemental IV Bolus Dose: 1mcg/kg every 2-5 min

W/ Isoflurane (0.4-1.5):
Usual: 0.25mcg/kg/min continuous IV infusion
Infusion Dose Range: 0.05-1.3mcg/kg/min
Supplemental IV Bolus Dose: 1mcg/kg every 2-5 min

DOSING CONSIDERATIONS

Elderly
>65 Years:
Starting dose should be decreased by 50%; then titrate cautiously

Discontinuation
No residual analgesic activity will be present w/in 5-10 min after discontinuation
For patients undergoing surgical procedures where postoperative pain is generally anticipated, alternative analgesics should be administered prior to discontinuation
Choice of analgesic should be appropriate for patient's surgical procedure and level of follow-up care

ADMINISTRATION

IV route

Inj site should be close to venous cannula and all IV tubing should be cleared at time of discontinuation of infusion
Continuous IV infusions should be administered only by an infusion device; refer to PI for individualized IV infusion rates

Preparation
Add 1mL of diluent per mg of remifentanil; shake well to dissolve
Dilute to a recommended final concentration of 20, 25, 50, or 250mcg/mL prior to administration; refer to PI for reconstitution/dilution info

Compatibility and Stability
Stable for 24 hrs at room temperature after reconstitution and further dilution to concentrations of 20-250mcg/mL w/ following IV fluids: sterile water for inj, D5 inj, D5 and 0.9% NaCl inj, 0.45% NaCl inj, lactated Ringer's inj
Shown to be compatible w/ propofol inj when coadministered into a running IV administration set
Not recommended in same IV tubing w/ nonspecific esterases in blood products

HOW SUPPLIED

Inj: 1mg, 2mg, 5mg

CONTRAINDICATIONS

Epidural or intrathecal administration, hypersensitivity to fentanyl analogs.

WARNINGS/PRECAUTIONS

IV bolus administration should be used only during the maintenance of general anesthesia. Interruption of infusion will result in rapid offset of effect. Use associated w/ apnea and respiratory depression. Not for use in diagnostic or therapeutic procedures outside the MAC setting. Resuscitative and intubation equipment, oxygen, and opioid antagonist must be readily available. May cause skeletal muscle rigidity, related to the dose and speed of administration. Bradycardia, hypotension, intraoperative awareness reported. Not recommended as sole agent for induction of anesthesia.

ADVERSE REACTIONS

N/V, hypotension, muscle rigidity, bradycardia, shivering, fever, dizziness, respiratory depression.

DRUG INTERACTIONS

Synergism w/ thiopental, propofol, isoflurane, and midazolam; reduce doses of these drugs by up to 75%.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Opioid analgesic.

PHARMACOKINETICS

Distribution: V_d=100mL/kg, 350mL/kg (initial, steady-state), plasma protein binding (70%). **Metabolism**: Hydrolysis via nonspecific blood and tissue esterases to carboxylic acid metabolite. **Elimination**: $T_{1/2}$=10-20 min.

ASSESSMENT

Assess for pulmonary disease, decreased respiratory reserve, hypersensitivity, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for cardiovascular depression (eg, bradycardia, hypotension), respiratory depression, muscle rigidity of neck and extremities, N/V, chills, arrhythmias, chest wall rigidity. Continuously monitor vital signs and oxygenation during administration. Appropriate postoperative monitoring should ensure adequate spontaneous breathing is established and maintained prior to discharge.

PATIENT COUNSELING

Advise to use caution while performing potentially hazardous tasks (eg, operating machinery/driving). Counsel about side effects of drug and abuse potential.

STORAGE

2-25°C (36-77°F).

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