Nalbuphine Hydrochloride (nalbuphine hydrochloride) - Drug Summary

Hospira Inc.

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Nalbuphine (nalbuphine hydrochloride)

THERAPEUTIC CLASS

Partial opioid agonist

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Moderate to Severe Pain

Opioid Nontolerant:
Usual: 10mg/70kg IV/IM/SQ; may repeat q3-6h prn
Max: 20mg/dose or 160mg/day

Adjust according to severity of pain, physical status, and concomitant agents

Opioid-Dependent:
Administer 1/4 of anticipated dose and observe for withdrawal signs

Preanesthetic

Preoperative and Postoperative Analgesia:

Opioid Nontolerant:
Usual: 10mg/70kg IV/IM/SQ; may repeat q3-6h prn
Max: 20mg/dose or 160mg/day

Adjust according to severity of pain, physical status, and concomitant agents

Opioid-Dependent:
Administer 1/4 of anticipated dose and observe for withdrawal signs

Anesthesia

Supplement to Balanced Anesthesia:
Induction: 0.3-3mg/kg IV over 10-15 min
Maint: 0.25-0.5mg/kg in single IV administrations prn

Labor Pain

Opioid Nontolerant:
Usual: 10mg/70kg IV/IM/SQ; may repeat q3-6h prn
Max: 20mg/dose or 160mg/day

Adjust according to severity of pain, physical status, and concomitant agents

Opioid-Dependent:
Administer 1/4 of anticipated dose and observe for withdrawal signs

ADMINISTRATION

IM/IV/SQ route

HOW SUPPLIED

Inj: 10mg/mL [1mL, 10mL], 20mg/mL [1mL, 10mL]

CONTRAINDICATIONS

Hypersensitivity to nalbuphine HCl or to any of the other ingredients in nalbuphine HCl injection.

WARNINGS/PRECAUTIONS

Should be administered as supplement to general anesthesia only by persons specifically trained in the use of IV anesthetics and management of the respiratory effects of potent opioids. Naloxone inj, resuscitative and intubation equipment, and oxygen should be readily available. Caution with emotionally unstable patients or history of opioid abuse. May develop tolerance or dependence; abrupt d/c following prolonged use may result in withdrawal symptoms. Episodes of abuse reported. May impair mental/physical abilities; caution in ambulatory patients. Severe fetal bradycardia reported when administered during labor and may occur earlier in pregnancy. Use in pregnancy or during labor and delivery only if clearly indicated and only if potential benefit outweighs risk to fetus/infant; monitor newborns for respiratory depression, apnea, bradycardia, and arrhythmias, and fetus for adverse effects. Increased risk of respiratory depression and CSF elevation with head injury, intracranial lesions, or preexisting increased intracranial pressure. May obscure the clinical course of patients with head injuries; use with extreme caution. May cause respiratory depression; use with caution at low doses with impaired respiration. Caution with renal or hepatic dysfunction; reduce dose. Caution with myocardial infarction with N/V. May cause spasm of the sphincter of Oddi; caution in patients about to undergo biliary tract surgery. Higher incidence of bradycardia reported during anesthesia in patients with no preoperative atropine.

ADVERSE REACTIONS

Sedation, sweating/clammy, N/V, dizziness/vertigo, dry mouth, headache.

DRUG INTERACTIONS

Possible additive effects with other opioid analgesics, general anesthetics, phenothiazines, or other tranquilizers, sedatives, hypnotics, or other CNS depressants (eg, alcohol); reduced dose of one or both agents when used in combination. Caution with mu agonist opioid analgesics (eg, morphine, oxymorphone, fentanyl); may precipitate withdrawal.

PREGNANCY AND LACTATION

Category B, caution in nursing.

MECHANISM OF ACTION

Synthetic opioid agonist-antagonist analgesic; kappa agonist/partial mu antagonist analgesic; binds to mu, kappa, and delta receptors.

PHARMACOKINETICS

Distribution: Crosses the placenta; found in breast milk. **Metabolism:** Liver. **Elimination:** Kidney; $T_{1/2}$=5 hrs.

ASSESSMENT

Assess for pain severity, physical status, or any other conditions where treatment is contraindicated or cautioned. Assess for pregnancy/nursing status, renal/hepatic function, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of drug abuse/dependence/tolerance, respiratory depression, withdrawal symptoms, hypersensitivity reactions, and other adverse reactions. If used during labor and delivery, monitor newborns for respiratory depression, apnea, bradycardia, and arrhythmias.

PATIENT COUNSELING

Inform that medication may impair physical/mental abilities; caution against performing hazardous tasks (eg, operating machinery/driving). Instruct to use as prescribed; advise not to increase dose or frequency without first consulting the physician. Inform that abrupt d/c after prolonged use or use with opioids may cause withdrawal symptoms. Counsel about the signs/symptoms of withdrawal and other adverse reactions. Advise to notify physician if pregnant or breastfeeding.

STORAGE

20-25°C (68-77°F). Protect from light. Store in carton until contents have been used.

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