

NAPHINE Inj

(Nalbuphine HCl 10mg)

? COMPOSITION

Each ampoule contains 10.0mg of Nalbuphine hydrochloride.

? INDICATIONS

Nalbuphine is indicated for the following diseases. Moderate to severe pain, a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery.

? DOSAGE & ADMINISTRATION

Adult : The usual dose is 10 mg for a 70 kg individual, administered subcutaneously, intramuscularly or intravenously; this dose may be repeated every 3 to 6 hours as necessary. The recommended single maximum dose is 20 mg, with maximum total daily dose of 160 mg. The use of Nalbuphine HCl as a supplement to balanced anesthesia requires induction doses of range from 0.3 mg/kg to 3mg/kg intravenously to be administered over a 10 to 15 minutes period with maintenance doses of 0.25 to 0.5mg/kg in single intravenous administrations. Dosage should be adjusted according to the severity of the pain, age, and other medication which the patient may be receiving. Patients who have been taking narcotics chronically may experience withdrawal upon the administration of Nalbuphine HCl. If unduly troublesome, narcotic withdrawal symptoms can be controlled by the slow intravenous administration of small increments of morphine, until relief occurs. If the previous analgesic was morphine, meperidine, codeine, or other narcotic with similar duration of activity, one-fourth of the anticipated of Nalbuphine HCl can be administered initially and the patient observed for signs of withdrawal, i. e., abdominal cramps, nausea, and vomiting, lacrimation, rhinorrhea, anxiety, restlessness, elevation of temperature or piloerection. If untoward symptoms do not occur, progressively larger doses may be tried at appropriate intervals until the desired level of analgesia is obtained with Nalbuphine HCl.

? PRECAUTIONS

1. Warning

This medicine transfers the placenta. Fetal and neonatal adverse effects that have been reported following the administration of Nalbuphine to the mother during labor include fetal bradycardia, respiratory depression. Therefore, Nalbuphine HCl should be used in with caution in women during labor and delivery.

2. Nalbuphine should not administer to the following patients.

The patients who are hypersensitive to Nalbuphine hydrochloride.

3. Caution should be observed in these patients

- 1) Emotionally unstable patients or for individuals with a history of narcotic abuse
- 2) Ambulatory patients who are driving a car or operating a machinery
- 3) Emergency procedure
- 4) During Labor and deliver
- 5) Head injury and intracranial pressure
- 6) Interaction with other central nervous system depressants
- 7) Patients with impaired respiration (e. g., respiratory depression, uremia, bronchial asthma, cyanosis, respiratory obstructions)
- 8) Renal dysfunction
- 9) Liver dysfunction
- 10) Patients with nausea or vomiting
- 11) Patients about to undergo surgery of the biliary tract

4. Adverse reactions

- 1) CNS effects : sedation, sweating, dizziness, nervousness, headache, depression, anxiety, abnormal crying, floating, gladness, hostility, idle fancy, confusion, faintness, hallucinations, feeling of heaviness, discomfort, insensibility, excitement, unreality
- 2) Cardiovascular effects : Hypertension, hypotension, bradycardia, tachycardia, pulmonary edema
- 3) Gastrointestinal effects : Nausea, vomiting, dry mouth, cramps, dyspepsia, hyperacidity, bitter taste
- 4) Respiratory effects : Depression, dyspnea, cyanosis, asthma
- 5) Dermatologic effects : Itching, burning, urticaria
- 6) Miscellaneous effects : Speech difficulty, urinary urgency, blurred vision,

flushing and warmth

5. General precaution

- 1) Nalbuphine hydrochloride is desirable not to administer to the patients of younger than 18 years.
- 2) Nalbuphine hydrochloride should be administered as a supplement to general anesthesia only by persons specifically trained in the use of intravenous anesthetics. Naloxone, resuscitative and intubation equipment and oxygen should be readily available.
- 3) Care should be taken to avoid increases in dosage or frequency of administration which in susceptible individuals might result in physical dependence. Abrupt discontinuation of Nalbuphine following prolonged use has been followed by symptoms of narcotic withdrawal i.e., abdominal cramps, nausea and vomiting, rhinorrhea, lacrimation, restlessness, anxiety, elevated temperature and piloerection. Therefore, the discontinuation should be slowly.
- 4) Nalbuphine should be administered with caution in patient about to under surgery of the biliary tract since it may cause spasm of the sphincter of Oddi.
- 5) Bradycardia has been reported in patients who did not receive atropine pre-operatively.

6. Drug Interaction

When Nalbuphine is used concomitantly with other CNS depressant, hypnotics, sedatives, phenothiazines or other tranquilizer, anesthetics, opiate analgesics, the dose should be decreased. since the adverse reaction may be seen.

7. Pregnancy

- 1) Since the safe use of nalbuphine during pregnancy has not been established, nalbuphine should not be administered to pregnant women unless the possible benefits outweigh the potential risks.
- 2) When nalbuphine is administered during labor and delivery, fatal respiratory depression may occur in the neonate.

8. Overdose

The administration of single dose of 72mg of Nalbuphine hydrochloride subcutaneously to eight normal subjects has been reported to have resulted primarily in symptoms of sleepiness and mild dysphoria. The immediate intravenous administration of Naloxone hydrochloride is a specific antidote. Oxygen, vasopressors and other supportive measures may be used.

? **STORAGE** : Hermetic container

? **USE TERM** : 3 years

? **PACKGE** : 10 Amps./Box

This drug is manufactured in accordance with Korea Good Manufacturing Practice(KGMP) as recommended by WHO.