Nabulex

Nalbuphine Hydrochloride

IM/IV Injection

Presentation
Nabulex IM/IV Injection: Each ampoule contains 2 ml sterile solution of Nalbuphine Hydrochloride INN 20 mg for IM/IV Injection.

Pharmacodynamic Properties
Nalbuphine Hydrochloride is a synthetic opioid agonist-antagonist analgesic of phenanthrene series. It is a potent analgesic and a supplement for balanced anesthesia. Nalbuphine Hydrochloride binds to mu, kappa and delta receptors. This is primarily a kappa agonist/ partial mu antagonist analgesic.

Pharmacokinetic Properties
Bioavailability: 81% (10 mg) and 83% (20 mg), intramuscular; 79% (10 mg) and 76% (20 mg) subcutaneous
Metabolism: 3 to 6 hours clinically, 5 hours in blood plasma

Indications
Nabulex is indicated for the relief of moderate to severe pain. It can also be used as a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery.

Dosage and Administration
Analgesia: Adult (>18 years.): 10 mg - 20 mg (for a 70 kg individual), administered intramuscularly or intravenously; this dose may be repeated every 3 to 6 hours as necessary. Dosage should be adjusted according to severity of the pain, physical status of the patient and other medications which the patient may be receiving. The maximum total daily dose is 160 mg.
As a supplement to balanced anesthesia: Induction doses range from 0.3 mg/kg to 3 mg/kg body weight intravenously to be administered over a 10 to 15 minute period with maintenance doses of 0.25 to 0.5 mg/kg in single intravenous administrations as required.

Contraindications
Contraindicated in patients with a known hypersensitivity to Nalbuphine Hydrochloride or any other ingredients of this medicine.

Precautions
This drug should be used carefully in patients with impaired respiration, impaired renal or hepatic function, myocardial infarction and biliary tract surgery. Patients receiving Nalbuphine Hydrochloride should not be engaged in activities requiring mental alertness and motor coordination, such as driving a car or operating machinery.
This drug should be administered as a supplement to general anesthesia only by trained persons.

Drug Interactions
Interactions described with other opioids may be anticipated. Patient receiving a narcotic analgesic, general anesthesia, phenothiazines or other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with Nalbuphine may exhibit an additive effect.

Use in Pregnancy and Lactation
Pregnancy Category B
There are no adequate and well-controlled studies in pregnant woman. Therefore this drug should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.
Limited data suggested that Nalbuphine Hydrochloride is excreted in human milk but in a small amount and with a clinically insignificant effect. So caution should be exercised when this drug is administered to a lactating mother.

Side Effects
Nausea, vomiting, constipation and drowsiness; larger doses may produce respiratory depression and hypotension; other side effects include difficulty with micturition, ureteric or biliary spasm, dry mouth, sweating, headache, facial flushing, vertigo, bradycardia, tachycardia, palpitations, postural hypotension, hypothermia, hallucinations, dysphoria, mood change, dependence, miosis, decreased libido or potency, rashes, urticaria and Pruritus.

Over Dose
The immediate intravenous administration of an opiate antagonist such as Naloxone or Nalmefene is a specific antidote. Oxygen, intravenous fluids, vasopressors and other supportive measures should be used as indicated. Sleepiness and mild dysphoria may occur due to overdose.

Storage Condition
Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack
Nabulex IM/IV Injection: Each box contains 1 blister pack of 1 ampoule of 2 ml sterile solution.

Manufactured by :
GENERAL Pharmaceuticals Ltd.
Unit-2, Gazipur, Bangladesh