Raltrox®

Nalbuphine Hydrochloride

Description
Nalbuphine hydrochloride (**Raltrox®**) is a synthetic opioid agonist-antagonist analgesic of the phenanthrene series. It is chemically related to the widely used opioid antagonist, naloxone, and the potent opioid analgesic, oxymorphone. The onset of action of Nalbuphine hydrochloride occurs within 2 to 3 minutes after intravenous administration, and in less than 15 minutes following subcutaneous or intramuscular injection.

Mode of Action
Nalbuphine hydrochloride (**Raltrox®**) is a potent analgesic. Its analgesic potency is essentially equivalent to that of morphine on a milligram basis. Nalbuphine is an agonist and antagonist at different opioid receptors. Nalbuphine is an agonist at kappa (κ) opioid receptors and an antagonist at mu(μ) receptors. It is without significant effects on delta (δ) opioid receptors.

Pharmacokinetics
The plasma half-life of Nalbuphine hydrochloride is 5 hours; Nalbuphine is distributed throughout the body, with a volume of distribution of 160-500 Litre. The duration of analgesic activity is 3 to 6 hours. The drug crosses the placenta and enters the foetal circulation. There is no information of the excretion of Nalbuphine in breast milk. The drug is extensively metabolized in the liver. The drug and its metabolites are excreted largely in the urine (70%) though some excretion into bile also occurs.

Composition
Raltrox® 1 ml Injection: Each ml contains concentrated solution of Nalbuphine Hydrochloride INN 10 mg. **Raltrox® 2 ml Injection:** Each 2 ml contains concentrated solution of Nalbuphine Hydrochloride INN 20 mg.

Indications
Raltrox® is indicated for the relief of moderate to severe pain. It can also be used as a supplement to balanced anesthesia, for pre-operative and post-operative analgesia, and for obstetrical analgesia during labor and delivery. It relieves moderate to severe pain associated with myocardial infarction.

Dosage and administration
Moderate to severe pain: By intravenous or intramuscular injection 10-20 mg for 70 kg patient, adjusted as required; Child upto 0.3 mg/kg repeated once or twice as necessary.
Pre-operative anesthesia: By intravenous or intramuscular injection 0.1-0.2 mg/kg.
Obstetrical analgesia during labor and delivery: By intravenous injection 0.3-1 mg/kg over 10-15 minutes with maintenance doses of 0.25-0.5 mg/kg in single intravenous administration as required.
Intraoperative analgesia: By intravenous injection 0.25-0.5 mg/kg at 30 minutes intervals.
Myocardial infarction: By slow intravenous injection 10-20 mg, repeated after 30 minutes if necessary. Larger dose is required when used as supplement for anesthesia than that required for analgesia.
Children from 18 months to 15 years old: Usually 0.2 mg/kg body-weight, given preferably by intravenous or intramuscular injection. Maintenance dose may be given at intervals of 4 to 6 hours or the dose must be determined by the physician.

Contraindications
Nalbuphine should not be administered to patients who are hypersensitive to it, or to any of the other ingredients in Nalbuphine.

Side effects
Generally Nalbuphine is well tolerated. The most frequent side effect is sedation. Less frequent reactions are sweating, nausea, vomiting, dizziness, vertigo, dry mouth, headache, respiratory depression, dyspnea, asthma, hypertension, hypotension, bradycardia and tachycardia.

Use in pregnancy and lactation
This drug should be used in pregnancy only if clearly needed, if the potential benefit outweighs the risk to the fetus, and if appropriate measures such as fetal monitoring are taken to detect and manage any potential adverse effect on the fetus. Severe foetal bradycardia has been reported when Nalbuphine is administered during labor. Naloxone may reverse these effects. Although there are no reports of foetal bradycardia earlier in pregnancy. Limited data suggest that Nalbuphine hydrochloride is excreted in maternal milk but only in a small amount with a clinically insignificant effect. Caution should be exercised when Nalbuphine is administered to a nursing woman.

Precautions
Caution should be taken in the following conditions: Impaired respiration, impaired renal or hepatic function, billiary tract surgery, myocardial infarction and hypotension.

Drug Interactions
No specific hazardous interactions have been identified, though excessive sedation may be produced by interaction with centrally acting depressants, including alcohol. Nalbuphine may precipitate withdrawal symptoms if it is given to patients who are physically dependent on opioid analgesic. The opioid agonist effects of Nalbuphine can be reversed by the specific competitive antagonist naloxone.

Overdosage
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 be happening due to overdose.

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

Packaging
Raltrox® 1 ml Injection: Each carton contains 3X1 ampoules in blister pack.
Raltrox® 2 ml Injection: Each carton contains 1 ampoule and 3 ml disposable syringe in plastic tray.

Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
Rupatali, Barishal, Bangladesh.

203-02