Radirif® 2

Nalbuphine Hydrochloride

Composition: Radirif® 2 injection : Each 2 ml injection contains Nalbuphine Hydrochloride INN 20 mg.

Pharmacology: Nalbuphine Hydrochloride is a synthetic potent analgesic. Its analgesic potency is essentially equivalent to that of morphine on a milligram basis. Receptor studies show that Nalbuphine binds to mu, kappa, and delta receptors, but not to sigma receptors. Nalbuphine is primarily a kappa agonist/partial mu antagonist analgesic.

The onset of action of Nalbuphine occurs within 2 to 3 minutes after intravenous administration, and in less than 15 minutes following subcutaneous or intramuscular injection. The plasma half-life of Nalbuphine is 5 hours, and in clinical studies the duration of analgesic activity has been reported to range from 3 to 6 hours.

Indication: Nalbuphine Hydrochloride is indicated for the relief of moderate to severe pain. It is used for relief of moderate to severe pain associated with myocardial infarction (MI). Nalbuphine Hydrochloride can also be used as a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery.

Dosage & Administration: The usual recommended adult 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. Dosage should be adjusted according to the severity of the pain, physical status of the patient, and other medications which the patient may be receiving.
Moderate to severe pain: by intravenous or intramuscular injection 10 - 20 mg for 70 kg patient, adjusted as required; child up to 0.3 mg/kg repeated once or twice as necessary.
Preoperative anesthesia: by intravenous or intramuscular injection 0.1-0.2 mg/kg.
Obstetrical analgesia during labor & 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 of 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 doses may be given at intervals of 4 to 6 hours or the dose must be determined by the physician.

Contraindication: Known hypersensitivity to Nalbuphine Hydrochloride

Side effects: Generally Nalbuphine is well tolerated. However, few side effects like sedation, sweating, nausea, vomiting, dizziness, vertigo, dry mouth, headache, respiratory depression, dyspnea and asthma may be seen.

Pregnancy & Lactation: Nalbuphine is pregnancy category B. The placental transfer of Nalbuphine is high and rapid. There are no well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Limited data suggest that Nalbuphine hydrochloride is excreted in maternal milk but only in a small amount (less than 1% of the administered dose) and with a clinically insignificant effect. Caution should be exercised when Nalbuphine Hydrochloride is administered to a nursing woman.

Drug interaction: No hazardous interactions have been identified with Nalbuphine; however, 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.

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

Overdose & treatment: Sleepiness & mild dyspnea may occur due to overdose. 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.

Storage: Keep it in a cool and dry place, protected from light and moisture.

How supplied: Radirif® 2 injection : Each box contains 4 mini-cartons and each mini-carton contains 1 ampoule in blister pack.

Manufactured by :

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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