Kinz® Injection
(Nalbuphine HCl)

DESCRIPTION:
Kinz® (Nalbuphine hydrochloride) is a synthetic narcotic agonist / antagonist analgesic of the phenanthrene series. It is chemically related to both the widely used narcotic antagonist, naloxone, and the potent narcotic analgesic,oxymorphone. **Kinz**® is a sterile solution suitable for subcutaneous, intramuscular or intravenous injection

COMPOSITION:
Kinz® **10mg Injection**
Each ml contains:
Nalbuphine HCl MS.....10mg

Kinz® **20mg Injection**
Each ml contains:
Nalbuphine HCl MS.....20mg

PHARMACOLOGY:
Kinz® is a potent analgesic. Its analgesic potency is essentially equivalent to that of morphine on a milligram basis. Receptor studies show that **Kinz**® bind to Mu, Kappa, and Delta receptors, but not to Sigma receptors. **Kinz**® is primarily a Kappa agonist / partial Mu antagonist analgesic

The onset of action of **Kinz**® 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

The narcotic antagonist activity of **Kinz**® is one-fourth as potent as nalorphine and 10 times that of pentazocine

Kinz® may produce the same degree of respiratory depression as equianalgesic doses of morphine. However, **Kinz**® exhibits a ceiling effect such that increases in dose greater than 30mg do not produce further respiratory depression in the absence of other CNS active medications affecting respiration

Kinz® by itself has potent narcotic antagonist activity at doses equal to or lower than its analgesic dose. When administered following or concurrent with Mu agonist opioid analgesics (e.g. morphine, oxymorphone, fentanyl). **Kinz**® may partially reverse or block narcotic-induced respiratory depression from the Mu agonist analgesic. **Kinz**® should be used with caution in patients who have been receiving Mu opioid analgesics on a regular basis

INDICATIONS AND USAGE:
Kinz® is indicated for the relief of moderate to severe pain. **Kinz**® can also be used as a supplement to balanced anaesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labour and delivery

CONTRAINDICATIONS / WARNINGS:
Kinz® should not be administered to patients who are hypersensitive to nalbuphine hydrochloride

Kinz® should be administered as a supplement to general anaesthesia only by persons specifically trained in the use of intravenous anaesthetic and management of the respiratory effects of potent opioids

Naloxone, resuscitative and intubation equipment and oxygen should be readily available

Caution should be observed in prescribing **Kinz**® for emotionally unstable patients, or for individuals with a history of narcotic abuse. Such patients should be closely supervised when long-term therapy is contemplated

Kinz® may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Therefore **Kinz**® shoud be administered with caution to ambulatory patients who should be warned to avoid such hazards. Maintain patient under observation until recovered from **Kinz**® effects that would affect driving or other potentially dangerous tasks
Pregnancy
Teratogenic Effects: Pregnancy Category B
Safe use of **Kinz**® in pregnancy has not been established. Although animal reproductive studies have not revealed teratogenic or embryotoxic effects, nalbuphine should be administered to pregnant women only if clearly needed
Use During Labor and Delivery
The placental transfer of nalbuphine is high, rapid and variable with a maternal to fetal ratio ranging from 1:0.37 to 1:6. Fetal and neonatal adverse effects that have been reported following the administration of nalbuphine to the mother during labor include fetal bradycardia, respiratory depression at birth, apnea, cyanosis and hypotonia. Maternal administration of naloxone during labor has normalised these effects in some cases. Severe and prolonged fetal bradycardia has been reported. Permanent neurological damage attributed to fetal bradycardia has occurred. A sinusoidal fetal heart rate pattern associated with the use of nalbuphine has also been reported. **Kinz**® should be used with caution in women during labor and delivery, and newborns should be monitored for respiratory depression, apnea, bradycardia and arrhythmias if **Kinz**® has been used
Head Injury and Increased Intracranial Pressure
The possible respiratory depressant effects and the potential of potent analgesics to elevate cerebrospinal fluid pressure (resulting from vasodilation following CO_2 retention) may be markedly exaggerated in the presence of head injury, intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, potent analgesics can produce effects which may obscure the clinical course of patients with head injuries. Therefore, **Kinz**® should be used in these circumstances only when essential, and then should be administered with extreme caution
Interaction
Although **Kinz**®possesses narcotic antagonist activity, there is evidence that in nondependent patients it will not antagonise a narcotic analgesic administered just before, concurrently, or just after an injection of **Kinz**®. Therefore, patients receiving a narcotic analgesic, general anaesthetics, phenothiazines, or other tranquilizers, sedatives, hypnotics, or other CNS depressants (Including alcohol) concomitantly with **Kinz**®may exhibit an additive effect. When such combined therapy is contemplated, the dose of one or both agents should be reduced

PRECAUTIONS:
Impaired Respiration
At the usual adult dose of 10mg/70kg. **Kinz**® causes some respiratory depression approximately equal to that produced by equal doses of morphine. However, in contrast to morphine, respiratory depression is not appreciably increased with higher doses of **Kinz**®. Respiratory depression induced by nalbuphine can be reversed by (Naloxone hydrochloride) when indicated. **Kinz**® should be administered with caution at low doses to patients with impaired respiration
Impaired Renal or Hepatic Function
Because **Kinz**® is metabolised in the liver and excreted by the kidneys. **Kinz**® should be used with caution in patients with renal or liver dysfunction and administered in reduced amounts
Myocardial Infarction
As with all potent analgesics, **Kinz**® should be used with caution in patients with myocardial infarction who have nausea or vomiting
Biliary Tract Surgery
As with all narcotic analgesics, **Kinz**® should be used with caution in patients about to undergo surgery of the biliary tract since it may cause spasm of the sphincter of Oddi
Cardiovascular System
During evaluation of **Kinz**® in anaesthesia, a higher incidence of bradycardia has been reported in patients who did not receive atropine preoperatively

SIDE EFFECTS:
Nausea / vomiting, dizziness / vertigo, dry mouth, headache, sedation, nervousness, depression, restlessness, crying, euphoria, floating, hostility, unusual dreams, confusion, faintness, hallucination, dysphoria, feeling of heaviness, numbness, tingling, unreality, hypotension, hypertension, bradycardia, tachycardia, cramps, dyspepsia, bitter taste, dyspnea, asthma, itching, burning, urticaria, speech difficulty, urinary urgency, blurred vision, flushing and warmth

180 mm

150mm

ALLERGIC REACTIONS:
Anaphylactic / anaphylactoid and other serious hypersensitivity reactions have been reported following the use of nalbuphine and may require immediate, supportive medical treatment. These reactions may include shock, respiratory distress, respiratory arrest, bradycardia, cardiac arrest, hypotension or laryngeal edema. Other allergic-type reactions reported include stridor, bronchospasm, wheezing, edema, rash, pruritus, nausea, vomiting, diaphoresis, weakness and shakiness

ADVERSE REACTIONS:
Pulmonary edema, agitation and injection site reactions such as pain, swelling, redness, burning and hot sensations

DRUG ABUSE / DEPENDENCE:
Kinz® has a low abuse potential. When compared with drugs which are not mixed agonist-antagonist, it has been reported that nalbuphine's potential for abuse would be less than that of codeine. Drug abuse has been reported infrequently. Psychological and physical dependence and tolerance may follow the abuse or misuse of nalbuphine

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 **Kinz**® following prolonged use has been followed by symptoms of narcotic withdrawal i.e. abdominal cramps, nausea, vomiting, rhinorrhoea, lacrimation, restlessness, anxiety, elevated temperature and piloerection

OVERDOSAGE:
The immediate intravenous administration of a narcotic antagonist such as naloxone or nalmefene is a specific antidote. Oxygen, intravenous fluids, vasopressors and other supportive measures should be used as indicated

DOSAGE AND ADMINISTRATION:

Children Dose 0.3mg / kg may be given initially, repeated once or twice as necessary
Adult Dose The usual recommended adult dose is 10mg for a 70kg 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. In nontolerant individuals, the recommended single maximum dose is 20mg with a maximum total daily dose of 160mg
Balanced Anaesthesia The use of **Kinz**® injection as a supplement to balanced anaesthesia requires larger doses than those recommended for analgesia. Induction doses of **Kinz**® range from 0.3mg/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 as required . The use of nalbuphine HCl injection may be followed by respiratory depression which can be reversed with the narcotic antagonist naloxone hydrochloride
Myocardial Infarction Dose of 10 to 30mg have been given by slow intravenous injection in myocardial infarction; a second dose of 20mg may be given after 30 minutes if necessary

OR
As directed by the physician

Kinz® is physically incompatible with nafcillin and ketorolac

PATIENTS DEPENDENT ON NARCOTICS:
Patients who have been taking narcotics chronically may experience withdrawal symptoms upon the administration of **Kinz**®. 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 dose of **Kinz**® 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 of 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 **Kinz**®

PATIENT INFORMATION:
Kinz® is associated with sedation and may impair mental and physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery

Kinz® is to be used as prescribed by a physician. Dose or frequency should not be increased without first consulting with a physician since **Kinz**® may cause psychological or physical dependence

The use of **Kinz**® with other narcotics can cause signs and symptoms of withdrawal

Abrupt discontinuation of **Kinz**® after prolonged usage may cause signs and symptoms of withdrawal

STABILITY:
See expiry on the pack

PRESENTATIONS:
Kinz® 10mg injection in pack of 5's
Kinz® 20mg injection in pack of 5's

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

کِنز انجکشن

(نلبیوفائن ہائیڈروکلورائیڈ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: انجکشن کے لیک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل

پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

P002066/S

R.N-04/HA/04/16/Inj.

180 mm

150mm