

AGORID

(Nalbuphine HCl) SPL

Injection

10mg/ml | 20mg/ml

COMPOSITION:

Agorid 10mg Injection:

Each 1ml ampoule contains: Nalbuphine HCl (SPL).....10mg

Agorid 20mg Injection:

Each 1ml ampoule contains: Nalbuphine HCl (SPL).....20mg

PHARMACOLOGY:

Nalbuphine is potent analgesic. Its analgesic potency is essentially equivalent to that of morphine on milligram basis. Receptor studies show that it binds to Mu, Kappa and Delta receptors.

Nalbuphine binds to kappa receptors in the central nervous system (CNS), thereby inhibiting the release of neurotransmitters that mediate pain, such as substance P. Additionally, Nalbuphine exerts post-synaptic inhibitory effects on interneurons and output neurons of the spinothalamic tract, responsible for transporting nociceptive information.

Nalbuphine antagonizes mu receptors, thereby potentially producing less intense respiratory depression as compared to opioid analgesics.

The onset of action occur within 2 to 3 minutes after intravenous administration and less than 15 minutes following subcutaneous or intramuscular injection.

INDICATIONS:

Nalbuphine is indicated for the relief of moderate to severe pain. Nalbuphine can also be used as supplement to balance anesthesia, for preoperative and post-operative analgesia and for obstetrical analgesia during labor and delivery.

CONTRAINDICATIONS:

AGORID (Nalbuphine HCl) should not be administered to patients who are hypersensitive to Nalbuphine HCl. It should be administered with caution in patients who have been receiving MU opioid analgesic on regular basis.

DOSAGE AND ADMINISTRATION:

Child Dose:

0.3mg/kg can be given repeated once or twice as necessary

Adult Dose:

The usual recommended adult dose is 10mg for 70kg individual administered subcutaneously, intravenously or intramuscularly. Dose may be repeated after 3 to 6 hours. Dosage should be adjusted according to the severity of pain and medication the patient is receiving. The recommended single maximum daily dose is 20mg with maximum total daily dose of 160mg.

To Balance Anesthesia:

The use of AGORID (Nalbuphine HCl) as a supplement to balance anesthesia requires larger doses than those recommended for analgesia. Induction doses of AGORID (Nalbuphine HCl) ranges from 0.3mg/kg to 3mg/kg IV, to be administered over a period of 10 to 15 minutes with maintenance doses of 0.25 to 0.5 mg/kg in single intravenous administration as required.

Myocardial Infarction:

Doses of 10 to 30mg should be given by slow intravenous injection in myocardial infarction, second dose of 20mg may be given after 30 minutes if necessary.

OVERDOSE:

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.

GENERAL PRECAUTIONS:

Impaired Respiration:

At usual adult dose of 10mg/70kg, AGORID(Nalbuphine HCl) may cause respiratory depression approximately equal to that produced by equal doses of morphine. Impaired respiration induced by AGORID (Nalbuphine HCl) can be reversed by Naloxone when indicated. AGORID (Nalbuphine HCl) should be administered at low doses to patients having already impaired respiration.

Impaired Renal and Hepatic Functions:

AGORID (Nalbuphine HCl) is metabolized in liver and excreted by kidney. Therefore, AGORID should be used with caution in patients with renal or liver dysfunction and administered in reduced amounts.

Myocardial Infarction:

AGORID (Nalbuphine HCl) should be used with caution in patient with myocardial infarction, who have nausea and vomiting.

Biliary Tract Surgery:

AGORID (Nalbuphine HCl) should be used with caution in patients who are undergoing surgery of biliary tract since it may cause spasm of the sphincter of Oddi.

Carcinogenesis:

No evidence of carcinogenicity was found in a 24 month carcinogenicity study at oral doses at recommended doses.

Nursing Mothers:

AGORID (Nalbuphine HCl) should be used with caution in nursing mothers.

WARNINGS:

AGORID (Nalbuphine HCl) should be administered as a supplement to general anesthesia only by persons specially trained in the use of intravenous anesthesia and management of respiratory effects of potent opioids

- AGORID (Nalbuphine HCl) should be administered with caution to ambulatory patients because it may impair mental or physical abilities required for tasks such as driving a car or operating machines.
- AGORID (Nalbuphine HCl) is pregnancy category B drug. Should be administered with care in pregnant women

DRUG INTERACTIONS:

Patient receiving narcotic analgesic, general anesthetics, tranquilizers, sedative and hypnotics or any CNS Depressants concomitantly with AGORID (Nalbuphine HCl) may exhibit additive effects.

AGORID (Nalbuphine HCl) is physically incompatible with nafcillin and ketorolac.

UNWANTED SIDE EFFECTS:

The most unwanted side effects in clinical studies were sedation and other less frequent were nausea, vomiting, dizziness, dry mouth and headache.

PRESENTATION:

AGORID 10mg/ml Injection: In pack of 5 ampoules x 1ml.

AGORID 20mg/ml Injection: In pack of 5 ampoules x 1ml.

INSTRUCTIONS:

Store at 15-30°C.

Protect from heat and light.

Keep all medicines out of the reach of children.

Avoid freezing. Injection should not be used if ampoule is leaking, solution is cloudy or contain undissolved particles.

To be sold on the prescription of a registered medical practitioner only.

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انجیکشن

ایگورڈ

(نالbufین ہائیڈروکلورائیڈ) انس پی ایل

خوراک: دواؤ اکڑ کی ہدایت کے مطابق استعمال کریں۔

ہدایت: دوا کو 30-15 سینٹی گریڈ پر رکھیں۔ گرمی اور روشنی سے محفوظ رکھیں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

نہجہ ہونے سے بچائیں۔ انجیکشن کے لیک ہونے، دھندلا ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی

صورت میں ہرگز استعمال نہ کریں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔



Manufactured by:

STANDPHARM PAKISTAN (PVT) LTD.

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