PRESCRIBING INFORMATION

سونوٹک 10 ملی گرام/20 ملی گرام انجکشن

SONOTIC® 10mg & 20mg Injection

(Nalbuphine Hydrochloride)

COMPOSITION
SONOTIC 10mg Injection
Each ml contains:
Nalbuphine Hydrochloride Brookes Specs.....10 mg
Mfg. Specs. Brookes

SONOTIC 20mg Injection
Each ml contains:
Nalbuphine Hydrochloride Brookes Specs.....20 mg
Mfg. Specs. Brookes

PHARMACOLOGY
Sonotic (Nalbuphine Hydrochloride) is chemically closely related to naloxone, the specific opioid antagonist and to oxymorphone a strong opioid. Sonotic (Nalbuphine Hydrochloride) is an agonist and antagonist at different opioid receptors with a spectrum of effects that resemble those of pentazocine. Sonotic (Nalbuphine Hydrochloride) is an agonist at kappa (k) opioid receptors and an antagonist at mu (μ) receptors. It is without significant effects on delta opioid receptors. Sonotic (Nalbuphine Hydrochloride) produces typical opioid effects in the central nervous system, such as analgesia and depression of respiration but may also act as an opioid antagonist.

CLINICAL PHARMACOLOGY
Given by intramuscular injection Sonotic (Nalbuphine Hydrochloride) is a powerful analgesic almost equipotent with morphine, 3 and 4 times as potent as pentazocine.

The usual parenteral dose is 10-20 mg by subsutaneous, intramuscular or intravenous injection. The onset of action is 2-3 minutes after intravenous injection and 15 minutes after intramuscular or subcutaneous administration the duration of action is 3-6 hours.

At usual therapeutic doses, Sonotic (Nalbuphine Hydrochloride) as a respiratory depressant has on effect equivalent to that of morphine. Unlike morphine, there appears to be a ceiling to both the respiratory depression and the analgesic action of Sonotic (Nalbuphine Hydrochloride) at single doses of 20 -30mg. Animal studies also indicate a ceiling to the anaesthetic sparing effect of Sonotic (Nalbuphine Hydrochloride). The respiratory depression may be reversed by naloxone.

Other opioid effect may occur including miosis and sedation, and less commonly nausea, vomiting, constipation, and psychotomimetic effects. Nalpubhine has minimal haemodynamic effects and in particular does not produce the adverse haemodynamic disturbances associated with pentazocine.

Opioid antagonist activity has been demonstrated in both animals and man. In morphine – dependent human subjects, Sonotic (Nalbuphine Hydrochloride) precipitated a typical nalorphine like abstinence syndrome and was ¼ as potent as nalorphine. Sonotic (Nalbuphine Hydrochloride) has also been used to reverse the respiratory depression caused by intraoperative opioids without affecting analgesia.

PHARMACOKINETICS
After intravenous administration of Sonotic (Nalbuphine Hydrochloride) the elimination half life is 2-4 hours and total body clearance is 1.42-1.50 $l.min^{-1}$ peak plasma concentration after intramuscular injection are achieved after 15-30 minutes. Sonotic (Nalbuphine Hydrochloride) is distributed through the body, with a volume of distribution of 160-500 l. The drug crosses the placenta and enters the fetal circulation producing concentrations comparable to those in maternal blood.

INDICATION
Relief of moderate to serve pain
Sonotic (Nalbuphine Hydrochloride) is effective in the relief of postoperative pain and in the treatment of pain associated with myocardial infarction. Subcutaneous or intramuscular administration of 10-20 mg produces an effect within 15 minutes and analgesia lasts 3- 5 hours. In this situation 10mg Sonotic (Nalbuphine Hydrochloride) has an equivalent effect to 80 or 90 mg of morphine.

In the management of pain caused by myocardial infarction slow intravenous injection of 20 mg may be repeated within 30 minutes. Sonotic (Nalbuphine Hydrochloride) 20 mg intravenously appears to produce an equivalent effect of diamorphine 5 mg intravenously. Sonotic (Nalbuphine Hydrochloride) has the advantage that it is free from the restrictions imposed by the misuse of drugs act which may make its availability easier in the emergency management of myocardial infarction before the patient reaches hospital.

There appears to be ceiling to the analgesic effect of Sonotic (Nalbuphine Hydrochloride) at 20-30mg in single doses. If satisfactory analgesia is obtained the dose may be repeated every 3-6 hours as necessary.

Chronic cancer pain has been treated by repeated intramuscular administration of Sonotic (Nalbuphine Hydrochloride) but the use of any parenteral analgesic in the routine long term management of cancer pain is not good practice regular strong opioid analgesics by mouth are preferable.

DOSAGE AND ADMINISTRATION
Sonotic (Nalbuphine Hydrochloride) is only available for parenteral use. The usual recommended dose is 10-20 mg for a 70 kg individual by subcutaneous, intramuscular or intravenous injection, repeated every 3-6 hours as necessary. The maximum recommended single dose in non-tolerant patients is 20 mg, and maximum daily dose 160 mg.

In children an initial dose of 0.3 mg/kg should be given (intramuscularly, intravenously or subcutaneously) and may be repeated once or twice as necessary. Although Sonotic (Nalbuphine Hydrochloride) as low abuse potential compared with morphine and other strong opioid agonists, dependence may develop with chronic use and withdrawal symptoms may occur if the drug is discontinued abruptly. Its abuse potential is similar to but probably less than that of pentazocine.

CONTRAINDICATIONS
The only absolute contraindication to the use of Sonotic (Nalbuphine Hydrochloride) is known sensitivity to the drug. Caution is required in the following circumstance.
1. Established respiratory depression.
2. Individuals physically dependent on opioid analgesics.
3. Conditions where clouding of consciousness is undesirable.
4. Raised intracranial pressure.

PRECAUTIONS
Established respiratory depression
In common with all drugs having opioid agonist activity Sonotic (Nalbuphine Hydrochloride) has respiratory depressant effect and at usual therapeutic doses this is similar to that of morphine. Care is required in patients with impaired respiratory drive.

Individuals physically dependent on opioid analgesics
Withdrawal effects may occur following administration of Sonotic (Nalbuphine Hydrochloride) to patients who are physically dependent on opioids because of its opioid antagonist action. Its use in such patients should therefore be avoided.

OVER DOSAGE
No cases of Sonotic (Nalbuphine Hydrochloride) overdose have been documented. The management of over dosage should be with the specific opioid antagonist naloxone and supportive measures, as for other strong opioid analgesics.

Severe or irreversible adverse effects
The abuse potential of Sonotic (Nalbuphine Hydrochloride) is similar to but probably less than that of pentazocine. There are, however, only isolated reports of misuse or abuse of Sonotic (Nalbuphine Hydrochloride).

Symptomatic adverse effects
The commonest adverse effect reported in clinical studies is sedation. This does not appear to be any more of a problem than with other strong opioid analgesics. The incidence of nausea and vomiting seems to be less than that associated with morphine. Psychotomimetic reactions are much less frequent than with pentazocine (estimated to be in the region of 1% overall compared with the 10-20% reported with pentazocine)

Other nonspecific effects (dizziness, sweating, dry mouth and headache) have been reported but in general Sonotic (Nalbuphine Hydrochloride) is well tolerated in usual therapeautic doses. There have been one or two reports of transient pain at the injection site following intramuscular or intravenous administration.

HIGH RISK GROUPS
Neonates
The drug is not recommended for use in neonates.

Children
There are some published reports on the use of Sonotic (Nalbuphine Hydrochloride) in children and the drug is licensed for such use. An initial dose of 0.3mg/kg should be given (intramuscularly, intravenously or subcutaneously) and may be repeated once or twice as necessary.

Lactating Mothers
Breast milk, there is no information on Sonotic (Nalbuphine Hydrochloride) and lactation but the use of the drug during lactation should be avoided.

Pregnant women
Sonotic (Nalbuphine Hydrochloride) is licensed for use in obstetric analgesia. However, no advantages in this indication have been established and experience is limited. Sonotic (Nalbuphine Hydrochloride) may produce respiratory depression in the neonates if used during labour and pregnancy.

STORAGE:
Store at temperature 15 ^{o}C to 30 ^{o}C away from light.

PRESENTATION:
Sonotic 10mg Injection Box of 10 x 1ml Ampoules
Sonotic 20mg Injection Box of 10 x 1ml Ampoules

طریقہ استعمال

سونوٹک انجکشن صرف عضلاتی وورید ی راستوں کے ذریعے مفید ہے

عمومی خوراک

بالغ افراد میں سونوٹک انجکشن 10 ملی گرام دن میں تین سے چار مرتبہ۔

انتہائی مقدار سونوٹک انجکشن 160 ملی گرام روزانہ دی جاسکتی ہے۔

بچوں میں سونوٹک انجکشن 0.3 ملی گرام فی کلوگرام دن میں ایک سے دومرتبہ روزانہ دی جاسکتی ہے۔

سونوٹک انجکشن نوزائیدہ بچوں میں قطعی طور پر ممنوع ہے

اسٹوریج:

15سے 30 ڈگری سینٹی گریڈ پر روشنی سے بچا کر رکھیں۔

brookes

Manufactured by:

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ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification