PRESCRIBING INFORMATION

Benorine® Injection (IM/IV)

بینورِن انجکشن

(Buprenorphine Injection BP)

COMPOSITION:
Each ml contains:
Buprenorphine as HCl….BP..... 0.3mg

DESCRIPTION:
Buprenorphine Injection is a clear, sterile, injectable agonist-antagonist analgesic intended for intravenous or intramuscular administration. Each ml of Buprenorphine injection contains 0.324 mg Buprenorphine hydrochloride (equivalent to 0.3 mg Buprenorphine),

CLINICAL PHARMACOLOGY:
Benorine (Buprenorphine Injection BP) is a parenteral opioid analgesic with 0.3 mg Buprenorphine being approximately equivalent to 10 mg morphine sulfate in analgesic and respiratory depressant effects in adults. Pharmacological effects occur as soon as 15 minutes after intramuscular injection and persist for 6 hours or longer. Peak pharmacologic effects usually are observed at 1 hour. When used intravenously, the times to onset and peak effect are shortened.
Benorine (Buprenorphine Injection BP) has elimination half-lives ranging from 1.2 to 7.2 hours (mean 2.2 hours) after intravenous administration of 0.3 mg of Benorine (Buprenorphine Injection BP) is metabolized by the liver and its clearance is related to hepatic blood flow.

Mechanism of Analgesic Action
Buprenorphine exerts its analgesic effect via high affinity binding to mu subclass opiate receptors in the central nervous system. Although Benorine (Buprenorphine Injection BP) may be classified as a partial agonist, under the conditions of recommended use it behaves very much like classical muagonists such as morphine. One unusual property of Buprenorphine observed in vitro studies is its very slow rate of dissociation from its receptor. This could account for its longer duration of action than morphine, the unpredictability of its reversal by opioid antagonists, and its low level of manifest physical dependence.

Narcotic Antagonist Activity
Benorine (Buprenorphine Injection BP) demonstrates narcotic antagonist activity and has been shown to be equipotent with naloxone as an antagonist of morphine.

Cardiovascular Effects
Benorine (Buprenorphine Injection BP) may cause a decrease or, rarely, an increase in pulse rate and blood pressure in some patients.

Effects on Respiration
Under usual conditions of use in adults, both Benorine (Buprenorphine Injection BP) and morphine show similar dose-related respiratory depressant effects.

Indications and Usage
Benorine (Buprenorphine Injection BP) injection is indicated for the relief of moderate to severe pain.

DOSAGE AND ADMINISTRATION

Adults
The usual dosage for persons 13 years of age and over is 1 ml Benorine injection (0.3 mg Buprenorphine) given by deep intramuscular or slow (over at least 2 minutes) intravenous injection at up to 6-hour intervals, as needed. Repeat once (up to 0.3 mg) if required, 30 to 60 minutes after initial dosage.

In high-risk patients (e.g., elderly, debilitated, presence of respiratory disease, etc.) and/or in patients where other CNS depressants are present, such as in the immediate postoperative period, the dose should be reduced by approximately one-half. Extra caution should be exercised with the intravenous route of administration, particularly with the initial dose.

Children
Buprenorphine to be used in children 2 to 12 years of age at doses between 2 to 6 mcg/kg of body weight given every 4 to 6 hours. There is insufficient experience to recommend a dose in infants below the age of two years,

Note:
It is a potent Narcotic analgesic. Benorine (Buprenorphine Injection BP) should be strictly used on the Prescription of Registered medical practioner

CONTRAINDICATIONS
Benorine (Buprenorphine Injection BP) injection should not be administered to patients who have been shown to be hypersensitive to the drug.

WARNINGS

Impaired Respiration
Benorine (Buprenorphine Injection BP) should be used with caution in patients with compromised respiratory function e.g., chronic obstructive pulmonary disease:
NALOXONE MAY NOT BE EFFECTIVE IN REVERSING THE RESPIRATORY DEPRESSION PRODUCED BY BUPRENORPHINE. THEREFORE, AS WITH OTHER POTENT OPIOIDS, THE PRIMARY MANAGEMENT OF OVERDOSE SHOULD BE THE RE-ESTABLISHMENT OF ADEQUATE VENTILATION WITH MECHANICAL ASSISTANCE OF RESPIRATION, IF REQUIRED.

Head Injury and Increased Intracranial Pressure
Benorine (Buprenorphine Injection BP), like other potent analgesics, may itself elevate cerebrospinal fluid pressure and should be used with caution in head injury, intracranial lesions and other circumstances where cerebrospinal pressure may be increased. Benorine (Buprenorphine Injection BP) can produce miosis and changes in the level of consciousness which may interfere with patient evaluation.

Use in Ambulatory Patients
Benorine (Buprenorphine Injection BP) may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Therefore, Benorine injection should be administered with caution to ambulatory patients who should be warned to avoid such hazards.
Use in Narcotic-Dependent Patients
Because of the narcotic antagonist activity of Benorine (Buprenorphine Injection BP), use in the physically dependent individual may result in withdrawal effects.

PRECAUTIONS
General
Benorine (Buprenorphine Injection BP) should be administered with caution in the elderly, debilitated patients, in children and those with severe impairment of hepatic, pulmonary, or renal function; myxedema or hypothyroidism; adrenal cortical insufficiency (e.g., Addison's disease); CNS depression or coma; toxic psychoses; prostatic hypertrophy or urethral stricture; acute alcoholism; delirium tremens; or kyphoscoliosis.
Information for Patients
The effects of Benorine (Buprenorphine Injection BP), particularly drowsiness, may be potentiated by other centrally acting agents such as alcohol or benzodiazepines. It is particularly important that in these circumstances patients must not drive or operate machinery. Buprenorphine has some pharmacologic effects similar to morphine which in susceptible patients may lead to self-administration of the drug when pain no longer exists.
Patients must not exceed the dosage of Benorine (Buprenorphine Injection BP) prescribed by their physician. Patients should be urged to consult their physician if other prescription medications are currently being used or are prescribed for future use.
Drug Interactions
Drug interactions common to other potent opioid analgesics also may occur with Benorine (Buprenorphine Injection BP) Particular care should be taken when Buprenorphine is used in combination with central nervous system depressant drugs
Pregnancy - Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Benorine (Buprenorphine Injection BP) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The safety of Benorine (Buprenorphine Injection BP) given during labor and delivery has not been established.
Nursing Mothers
Breast-feeding is therefore not advised in nursing mothers treated with Benorine (Buprenorphine Injection BP)
Pediatric Use
The safety and effectiveness of Buprenorphine have been established for children between 2 and 12 years of age. It is of similar effectiveness in children as in adults.

ADVERSE REACTIONS
The most frequent side effect is sedation which occurred in approximately two-thirds of the patients. Although sedated, these patients could easily be aroused to an alert state.
Other less frequent adverse reactions occurring in 5 to 10% of the patients were:
Nausea, Dizziness/Vertigo
Occurring in 1 to 5% of the patients:
Sweating, Headache, Hypotension, Nausea/Vomiting, Vomiting, Hypoventilation and Miosis
The following adverse reactions were reported to have occurred in less than 1% of the patients:
CNS Effect: confusion, blurred vision, euphoria, weakness/fatigue, dry mouth, nervousness, depression, slurred speech, paresthesia, Hypertension, tachycardia, constipation, dyspnea, cyanosis, pruritus, visual abnormalities, hallucinations, depersonalization, tremor, and pallor.

DRUG ABUSE AND DEPENDENCE
Benorine (Buprenorphine Injection BP) is a partial agonist of the morphine type; i.e., it has certain opioid properties which may lead to psychic dependence of the morphine type due to an opiate-like euphoric component of the drug. Direct dependence studies have shown little physical dependence upon withdrawal of the drug. However, caution should be used in prescribing to individuals who are known to be drug abusers or ex-narcotic addicts. The drug may not substitute in acutely dependent narcotic addicts due to its antagonist component and may induce withdrawal symptoms.

STORAGE:
Store at temperature 15 to 30 °C away from light.

PRESENTATION:
Benorine (Buprenorphine Injection BP) is available in a box of 5x1ml ampoules.

brookes

Manufactured by:

Brookes Pharma Private Limited
58 - 59 Sector 15 Korangi Industrial Area
Karachi 74900 Pakistan.

ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification

مقدار اور طریقہ استعمال:

بڑوں میں: 13 سال سے بڑی عمر کے مریضوں میں بینورن 1ml (0.3mg) انجکشن پٹھوں میں یا آہستہ آہستہ سے 2 منٹ میں وریدی راستہ سے دیا جاسکتا ہے۔ بینورن انجکشن (6) چھ گھنٹے کے وقفے سے دوبارہ دیا جاتا ہے۔ تکلیف کی شدت کی صورت میں 30 سے 60 منٹ کے بعد دوبارہ دیا جاسکتا ہے۔

بوڑھوں میں اور سانس کی بیماری کی صورت میں خوراک کو آدھا دینا چاہیئے

بچوں میں: 2 سے 12 سال کے بچوں میں بینورن انجکشن کی مقدار 2 سے 6 مائیکروگرام/کلوگرام جسمانی وزن کے حساب سے ہر 6 گھنٹے بعد، دو سال سے کم عمر میں بینورن انجکشن نہیں لگانا چاہیئے۔

احتیاط: بینورن ایک موثر نشہ آور دوا ہے اس کے بے وجہ استعمال سے مریض عادی ہو جاتا ہے لہٰذا اسکو مستند ڈاکٹر کی ہدایت پر استعمال کریں۔

اسٹوریج: 15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیئے۔