Buepron® Injection
(Buprenorphine)

Description:
Buprenorphine is opioid analgesic. Its molecular formula is $C_{29}H_{41}NO_4HCl$

COMPOSITION:
Each ml contains: Buprenorphine Hydrochloride BP
equivalent to Buprenorphine…..0.3mg

Clinical Pharmacology:
Pharmacological effects occur as soon as 15minutes after intramuscular injection and persist for 6 hours or longer. Peak pharmacologic effects usually are observed at 1hour. When used intravenously, the time to onset and peak effect is shortened The limits of sensitivity of available analytical methodology precluded demonstration of bioequivalence between intramuscular and intravenous routes of administration. Elimination half life ranges from 1.2 - 7.2 hours (mean 2.2 hours) after intravenous administration of 0.3mg of Buprenorphine
Buprenorphine 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 μ subclass opiate receptors in the central nervous system. Although Buprenorphine may be classified as partial agonist, under the conditions of recommended use it behaves very much like classical μ agonists such as morphine. One unusual property of Buprenorphine observed is its very slow rate of dissociation from its receptor

Narcotic Antagonist Activity:
Buprenorphine demonstrates narcotic antagonist activity and has been shown to equipotent with naloxone as an antagonist of morphine in the mouse tail flick test

Cardiovascular Effects:
Buprenorphine may cause a decrease or rarely, an increase in pulse rate and blood pressure in some patients

Effects on Respiration:
Under usual condition of use in adults, both Buprenorphine and morphine show similar dose-related respiratory depressant effects

INDICATIONS AND USAGE:
Buepron® (Buprenorphine) is indicated for the relief of moderate to severe pain

CONTRA-INDICATIONS:
Buprenorphine should not be administered to patients who have been shown to be hypersensitive to the drug

WARNINGS:
Impaired Respiration:
As with other potent opioids, clinically significant respiratory depression may occur within the recommended dose range in patients receiving therapeutic doses of Buprenorphine. It should be used with caution in patients with compromised respiratory function. Particular caution is advised if it is administered to patients taking or recently receiving drugs with CNS / respiratory depressant effects. In patients with the physical and/or pharmacological risk factors above, the dose should be reduced by approximately one-half

Interactions with other CNS depressants:
Patients receiving Buprenorphine in the presence of other narcotic analgesics, general anesthesia, antihistamines, benzodiazepines, phenothiazines, other tranquilizers, sedative/hypnotics or other CNS depressants may exhibit increased CNS depression. In such cases, it is particularly important that the dose of one or both agents be reduced

Head Injury and Increased Intracranial Pressure:
Buprenorphine, 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

Use in Ambulatory Patients:
Buprenorphine may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Therefore, it 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 Buprenorphine, use in the physically dependent individual may result in withdrawl effects

PRECAUTIONS:
General:
Buprenorphine should be administered with caution in the elderly, debilitated patients, in children and those with severe impairment of hepatic, pulmonary, or renal functions; myxedema or hypothyroidism; adrenal cortical insufficiency; CNS depression or coma; toxic psychoses; prostatic hypertrophy or urethral structure; acute alcoholism; delirium tremens; or kyphoscoliosis
Because Buprenorphine is metabolized by the liver, the activity of Buprenorphine may be increased and/or extended in those individuals with impaired hepatic function or those receiving other agents known to decrease hepatic clearance. It should be administered with caution in patients with dysfunction of the biliary tract

Pregnancy:
Pregnancy Category C

Labor and Delivery:
The safety of Buprenorphine given during labor and delivery has not been established

Nursing Mothers:
Buprenorphine passes into the mother's milk. Breast-feeding is therefore not advised in nursing mothers treated with Buprenorphine

Paediatric Use:
The available information provides reasonable evidence that Buprenorphine may be used safely in children ranging from 2-12 years of age, and that it is of similar effectiveness in children as in adults

ADVERSE REACTIONS:
Drowsiness, sleep, nausea, vomiting, dizziness, sweating, hallucination and other psychotomimetic effects. Hypotention leading to syncope may occur. Rashes, headache, urinary retention and blurring of vision have occasionally been reported. Rarely, allergic reaction may occur following a single dose

DRUG ABUSE AND DEPENDENCE:
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. Caution should be used in prescribing to individuals who are known to be drug abusers or ex-narcotic addicts

DOSAGE:
Adults and children over 12years old: The usual dosage is 1ml given by deep intramuscular or slow (over atleast 2minutes) intravenous injection at up to 6hours intervals, as needed. Repeat once (up to 0.3mg) if required, 30 to 60minutes after initial dosage. In high risk patients the dose should be reduced approximately one-half

Occasionally, it may be necessary to administered single doses of up to 0.6mg to adults depending upon the severity of the pain and the response of the patient. This dose should only be given IM and only to patients who are not in high risk category

Children (2 – 12years of age): Buprenorphine is used in children 2 – 12years of age at doses between 2-6 micrograms/kg of body weight given every 4-6 hours Or as directed by the physician

Presentation:
Buepron® Injection 0.3mg/ml in pack of 5's

Instructions:
Keep out of reach of children
Avoid exposure to heat and light
Store at 25ºC or below
Improper storage may deteriorate the medicine

Cautions:
Avoid freezing and Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particles

بیوپرون انجکشن
(بپرینارفین)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ اور گرمی سے محفوظ اور ڈگری سینٹی گریڈ
یا اس سے کم درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی
تنبیہ: منجمد ہونے سے بچائیں اور انجکشن کے لیک ہونے، دُھندلا ہونے
یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

Manufactured by:
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