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Buprenex (Buprenorphine)

??? ??????: 30 ??????/?????? 2017

The most frequent side effect in clinical studies involving 1,133 patients was 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 5-10% of the patients were:	
Dizziness/Vertigo	Nausea
Occurring in 1-5% of the patients:	
Headache	Sweating
Nausea/Vomiting	Hypotension
Hypoventilation	Vomiting Miosis

The following adverse reactions were reported to have occurred in less than 1% of the patients:

confusion, blurred vision, euphoria, weakness/fatigue, dry mouth, nervousness, depression, slurred speech, paresthesia.**CNS Effect:**

hypertension, tachycardia, bradycardia. **Cardiovascular:**

constipation. **Gastrointestinal:**

dyspnea, cyanosis. **Respiratory:**

pruritus. **Dermatological:**

diplopia, visual abnormalities. **Ophthalmological:**

injection site reaction, urinary retention, dreaming, flushing/warmth, chills/cold, tinnitus, conjunctivitis, Wenckebach block, and psychosis.**Miscellaneous:**

Other effects observed infrequently include malaise, hallucinations, depersonalization, coma, dyspepsia, flatulence, apnea, rash, amblyopia, tremor, and pallor.

The following reactions have been reported to occur rarely: loss of appetite, dysphoria/agitation, diarrhea, urticaria, and convulsions/lack of muscle coordination.

Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in the post-marketing experience of **Allergic Reactions:** Buprenex and other buprenorphine- containing products. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported. A history of hypersensitivity to buprenorphine is a contraindication to Buprenex.

In the United Kingdom, buprenorphine hydrochloride was made available under monitored release regulation during the first year of sale, and yielded data from 1,736 physicians on 9,123 patients (17,120 administrations). Data on 240 children under the age of 18 years were included in this monitored release program. No important new adverse effects attributable to buprenorphine hydrochloride were observed.

Drug Abuse And Dependence

Buprenorphine hydrochloride 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.