Butorphic® Injection CIV  
(butorphanol tartrate)

Opiate agonist-antagonist for 3 to 4 hour pain relief.

Butorphic® provides the convenience of a 20 mL Vial
- Lower inventory cost
- Less chance of vial puncture contamination
- Fewer expiry worries
- Less time exposed to extreme field storage conditions
- Unparalleled dosing economy
- Manufactured in the U.S.A.

Butorphanol tartrate, opiate agonist-antagonist, has long been a staple in veterinary medicine for fast-acting relief of moderate to severe pain.

The Butorphic® brand provides you with the quality clinical performance you demand and the unprecedented economic advantage you expect from Akorn Animal Health.
Butorphic® C
(butorphanol tartrate injection)

CAUTION
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION
Butorphic (butorphanol tartrate) injection is a totally synthetic centrally acting, narcotic agonist-antagonist analgesic with potent antispasmodic activity. It is a member of the phenanthrene series. The chemical name is Morphinan-3, 14-diol, 17-(cyclobutylimethyl)-y]-(-)-(S)-R,R)-2,3-dihydroxybutanedioic acid (1:1) (salt). It is a white, crystalline, water soluble substance having a molecular weight of 477.55; its molecular formula is C_{21}H_{29}NO_{2}•C_{4}H_{6}O_{6}.

Chemical Structure:

Each mL of Butorphic Injection contains butorphanol base (as butorphanol tartrate, USP) 10 mg, 3.3 mg citric acid, USP, 6.4 mg sodium citrate, USP, 4.7 mg sodium chloride, USP, and 0.1 mg benzethonium chloride, USP, q.s. with water for injection, USP.

CLINICAL PHARMACOLOGY

Comparative Pharmacology

In animals, butorphanol has been demonstrated to be 4 to 30 times as potent as morphine and 20 times that of pentazocine. 1, 2, 3

In ponies, butorphanol given intramuscularly at a dosage of 0.22 mg/kg was shown to alleviate experimentally induced visceral pain for about 4 hours. 9

In horses, intravenous dosages of butorphanol ranging from 0.05 to 0.4 mg/kg were shown to be effective in alleviating visceral and superficial pain for at least four hours, as illustrated in the following figure:

*Pain threshold in butorphanol-treated colicky horses relative to placebo controls
A definite dosage-response relationship was detected in that butorphanol dosage of 0.1 mg/kg was more effective than 0.05 mg/kg but not different from 0.2 mg/kg in alleviating deep abdominal pain.

Acute Equine Studies

Rapid intravenous administration of butorphanol at a dosage of 2.0 mg/kg (20 times the recommended dosage) to a previously unmedicated horse resulted in a brief episode of inability to stand, muscle fasciculation, a convulsive seizure of 6 seconds duration, and recovery within three minutes. The same dosage administered after 10 successive daily 1.0 mg/kg dosages of butorphanol resulted only in transient sedative effects. During the 10 day course of administration at 1.0 mg/kg (10 times the recommended use level) in two horses, the only detectable drug effects were transient behavioral changes typical of narcotic agonist activity. These included muscle fasciculation about the head and neck, dysphoria, lateral nystagmus, ataxia, and salivation. Repeated administration of butorphanol at 1.0 mg/kg (10 times the recommended dose) every four hours for 48 hours caused constipation in one of two horses.

Subacute Equine Studies

Horses were found to tolerate butorphanol given intravenously at dosages of 0.1, 0.3, and 0.5 mg/kg every 4 hours for 48 hours followed by once daily injections for a total of 21 days. The only detectable drug effects were slight transient ataxia observed occasionally in the high dosage group. No clinical, laboratory, or gross or histopathologic evidence of any butorphanol-related toxicity was encountered in the horses.

INDICATIONS

Butorphic (butorphanol tartrate) Injection is indicated for the relief of pain associated with colic in adult horses and yearlings. Clinical studies in the horse have shown that butorphanol tartrate alleviates abdominal pain, associated with torsion, impaction, intussusception, spasmodic and tympanic colic, and postpartum pain.

WARNINGS

DO NOT USE IN HORSES INTENDED FOR HUMAN CONSUMPTION.

CAUTION

Butorphic injection, a potent analgesic, should be used with caution with other sedative or analgesic drugs as these are likely to produce additive effects.

There are no well-controlled studies using butorphanol in breeding horses, weanlings, and foals. Therefore, the drug should not be used in these groups.

ADVERSE REACTIONS

In clinical trials in horses, the most commonly observed side effect was slight ataxia which lasted 3 to 10 minutes. Marked ataxia was reported in 1.5% of the 327 horses treated. Mild sedation was reported in 9% of the horses.

DOSEAGE

The recommended dosage in the horse is 0.1 mg of butorphanol per kilogram of body weight (0.05 mg/lb) by intravenous injection. This is equivalent to 5 mL of Butorphic Injection for each 1000 lbs body weight. The dose may be repeated within 3 to 4 hours but treatment should not exceed 48 hours. Preclinical model studies and clinical field trials in horses demonstrate that the analgesic effects of butorphanol tartrate are seen within 15 minutes following injection and persist for about 4 hours.

HOW SUPPLIED

Butorphic (butorphanol tartrate) Injection, 10 mg base activity per mL
NDC 59399-112-20 20 mL vial in package of one
NDC 59399-112-50 50 mL vial in package of one

STORAGE

Store at controlled room temperature 20° to 25°C (68° to 77°F). Protect from light.

REFERENCES


Manufactured by:
Akorn, Inc.
Lake Forest, IL 60045

NOT FOR PRESCRIBING PURPOSES. PLEASE REFER TO PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.