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® CIV (butorphanol tartrate injection)**

**DESCRIPTION:** 10 mg Butorphanol base per mL as Butorphanol Tartrate

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Purchase from Your Distributor of Choice

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

ANADA # 200-332, Approved by FDA

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Butorphic® IV
(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 antinflamatory activity. It is a member of the phenanthrene series. The chemical name is Morphinan-3, 14-diol, 17-cyclobutylyl(1, 1)-(S-[(R, R)]-2,3-dihydroxybutanediol (1:1) (salts). It is a white, crystalline, water soluble substance having a molecular weight of 477.55; its molecular formula is C21H29NO2+C4H6O6.

Chemical Structure:

Each ml of Butorphic Injection contains butorphanol base (as butorphanol tartrate) USP 10 mg, 3.3% 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 more potent than morphone and pentazocine (Talwin®-IV) respectively.1 In humans, butorphanol has been shown to have 5 to 7 times the analgesic activity of morphone and 20 times that of pentazocine.2,3 Butorphanol has 15 to 20 times the oral antinflamatory activity of codeine or dextromethorphan in dogs and guinea pigs.4-6
As an antagonist, butorphanol is approximately equivalent to nalorphine and 30 times more potent than pentazocine.1
Cardiopulmonary depressant effects are minimal after treatment with butorphanol as demonstrated in dogs,7,8,9 and horses,10,11 Unlike classical narcotic agonist analgesics which are associated with decreases in blood pressure, reduction in heart rate, and concomitant release of histamine, butorphanol does not cause histamine release.11 Furthermore, the cardiopulmonary effects of butorphanol are not distinctly dosage related but rather reach a ceiling effect beyond which further dosage increases result in relatively lesser effects. Reproduction: Studies performed in mice and rabbits revealed no evidence of impaired fertility or harm to the fetus due to butorphanol tartrate. In the female rat, parenteral administration was associated with increased nervousness and decreased care for the newborn, resulting in a decreased survival rate of the newborn. This nervousness was seen only in the rat species.

Equine Pharmacology
Following intravenous injection in horses, butorphanol is largely eliminated from the blood within 3 to 4 hours. The drug is extensively metabolized in the liver and excreted in the urine.
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:

DOSAGE
The recommended dosage in the horse is 0.1 mg of butorphanol per kilogram of body weight (0.05 mg/ml) 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. Pre-clinical 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

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

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 8% of the horses.