

Approval Date: MAY 1 - 2008

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-332

**BUTORPHIC Injection
(butorphanol tartrate)**

**Indications for use: For the relief of pain associated with colic and
postpartum pain in horses.**

Sponsored by:

Lloyd, Inc.

CW0829

FOIS

FREEDOM OF INFORMATION SUMMARY

1. General Information:

- a. File Number: ANADA 200-332
- b. Sponsor: Lloyd, Inc.
604 W. Thomas Ave.
Shenandoah, Iowa 51601

Drug Labeler Code: 061690
- c. Established Name: Butorphanol tartrate
- d. Proprietary Name: BUTORPHIC Injection
- e. Dosage Form: Solution
- f. How Supplied: 20 mL vials
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: 10 mg butorphanol base per mL as butorphanol tartrate
- i. Route of Administration: Intravenous injection
- j. Species/Class: Horses
- k. Recommended Dosage: The recommended dosage in the horse is 0.1 mg butorphanol per kilogram of body weight (0.05 mg/lb) by intravenous injection. The dose may be repeated within 3 to 4 hours but treatment should not exceed 48 hours.
- l. Pharmacological Category: Analgesic
- m. Indications: Butorphanol Injection is indicated for relief of pain associated with colic in adult horses and yearlings. Clinical studies in the horse have shown that Butorphanol Injection alleviates abdominal pain associated with torsion, impaction, intussusception, and tympanic colic, and postpartum pain.

n. Pioneer Product: TORBUGESIC; butorphanol tartrate; NADA 135-780; Fort Dodge Animal Health, Division of Wyeth

2. TARGET ANIMAL SAFETY AND EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Lloyd, Inc., was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product BUTORPHIC (butorphanol tartrate) Injection. The generic product is administered as an intravenous injectable, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, TORBUGESIC (butorphanol tartrate), the subject of Fort Dodge Animal Health, Division of Wyeth, NADA 135-780, was approved on June 11, 1985.

3. HUMAN SAFETY:

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that the generic product BUTORPHIC Injection, when used under their proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-332:

BUTORPHIC Injection – vial and carton labels – 20 mL; package insert

Pioneer Labeling for NADA 135-780:

TORBUGESIC – vial and carton labels – 50 mL; package insert

DOSAGE: By intravenous injection, 0.1 mg per kg body weight (0.05 mg per lb body weight) every 6 to 8 hours, to a maximum of 4 mg per kg (1.8 mg per lb) body weight. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours.

Store in original container at room temperature 15°C (59°F) to 30°C (86°F).

FOR USE IN HORSES ONLY

NOT FOR USE IN HORSES INTENDED FOR FOOD.

READ PACKAGE INSERT

Manufactured by
Akorn, Inc., Des Plaines, IL 60018

Butorphanic™

INJECTION
BUTORPHANOL
TARTRATE

Veterinary Injection

contains 10 mg

butorphanol base per mL as

Etorphanol tartrate

20 mL

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

ANADA 200-332, Approved by FDA

Each mL of solution contains:
butorphanol base as butorphanol tartrate USP..... 10 mg
butorphanol base as butorphanol tartrate USP..... 10 mg
Cholic acid USP..... 3.3 mg
Sodium citrate USP..... 8.4 mg
Sodium chloride USP..... 2.7 mg
Water for Injection USP..... 10.7 mg

Manufactured for:

LLOYD
LABORATORIES

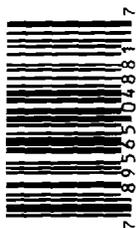
A Division of LLOYD, Inc.

Shenandoah, Iowa 51601

U.S.A.

List No. 4891 — 20 mL

ButorphanolTM
INJECTION
BUTORPHANOL
TARTRATE
Veterinary Injection



0108

Manufactured for:



Shenandoah, Iowa
51801, U.S.A.
List No. 4881 --- 20 mL

DOSAGE: By intravenous injection, 0.1 mg per kg body weight (0.05 mg/lb). This is equivalent to 5 mL for each 1000 lbs of body weight. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours.

FOR USE IN HORSES ONLY

NOT FOR USE IN
HORSES INTENDED
FOR FOOD.

READ PACKAGE INSERT

ButorphanolTM

INJECTION

BUTORPHANOL
TARTRATE
Veterinary Injection

contains 10 mg
butorphanol base per mL as
butorphanol tartrate

20 mL

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

ANADA 200-332, Approved by FDA

Each mL of solution contains:
Butorphanol base (as butorphanol tartrate USP).....10 mg
Citric acid USP.....3.3 mg
Sodium citrate USP...6.4mg
Sodium chloride USP.....4.7 mg
Benzethonium chloride USP.....0.1 mg
Water for injection USP.....q.s.

Store at controlled room temperature 15°C to 30°C (59° to 86°F).

Manufactured by
Akorn, Inc., Decatur, IL
62522

- 7 Popio, K.A. *et al*: Hemodynamic and Respiratory Effects of Morphine and Butorphanol. *Clin. Pharm. Ther.* 23:281-287, 1978.
- 8 Robertson, J.T. and Muir, W.W.: Cardiopulmonary Effects of Butorphanol Tartrate in Horses. *Am. J. Vet. Res.* 42:41-44, 1981.
- 9 Kalpravidh, M. *et al*: Effects of Butorphanol, Flunixin, Levorphanol, Morphine, Pentazocine and Xylazine in Ponies. *Am. J. Vet. Res.* 45:217-223, 1984.

Butorphic™ INJECTION

Butorphanol Tartrate
Veterinary Injection



Manufactured for



Shenandoah, Iowa 51601 U.S.A.

Manufactured by
Akorn, Inc.,
Decatur, IL 62522

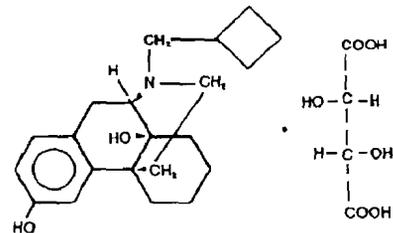
CAUTION

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

DESCRIPTION

Butorphic Injection (butorphanol tartrate) is a totally synthetic, centrally acting, narcotic agonist-antagonist analgesic with potent antitussive activity. It is a member of the phenanthrene series. The chemical name is Morphinan-3, 14-diol, 17-(cyclobutylmethyl)-,(-)-(S-(R*,R*))-2,3-dihydroxybutanedioate (1:1)(salt). It is a white, crystalline, water soluble substance having a molecular weight of 477.55; its molecular formula is $C_{21}H_{29}NO_2 \cdot C_4H_6O_6$.

Chemical Structure:



Each mL of Butorphic Injection contains 10 mg butorphanol base (as tartrate), 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 more potent than morphine and pentazocine (Talwin®-V) respectively.¹ In humans, butorphanol has been shown to have 5 to 7 times the analgesic activity of morphine and 20 times that of pentazocine.^{2,3} Butorphanol has 15 to 20 times the oral antitussive activity of codeine or dextromethorphan in dogs and guinea pigs.⁴

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 dogs⁵, humans^{6,7} and horses.⁸ 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.¹ 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.

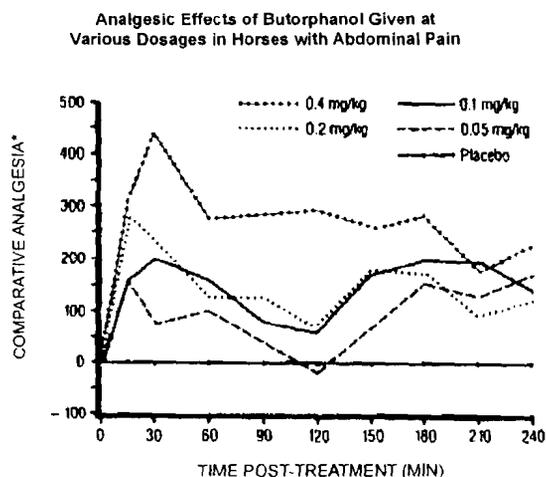
Reproduction: Studies performed in mice and rabbits revealed no evidence of impaired fertility or harm to the fetus due to butorphanol tartrate. In the female rat, parenteral administration was associated with increased nervousness and decreased care for the newborn, resulting in a decreased survival 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:



*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

Butorphanol 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 Injection alleviates abdominal pain associated with torsion, impaction, intussusception, spasmodic and tympanic colic, and postpartum pain.

WARNINGS

NOT FOR USE IN HORSES INTENDED FOR FOOD. NOT FOR HUMAN USE.

CAUTION

Butorphanol 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.

DOSAGE

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 Butorphanol 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 Injection are seen within 15 minutes following injection and persist for about 4 hours.

SUPPLY

20 mL vials Butorphanol Injection (butorphanol tartrate) veterinary injection, 10 mg base activity per mL. List No. 4881.

STORAGE

Store at controlled room temperature 15° to 30° C (59° to 86° F).

REFERENCES

- 1 Pircio, A. W. *et al*: The Pharmacology of Butorphanol. *Arch. Int. Pharmacodyn. Ther.* 220(2):231-257, 1976.
- 2 Dobkin, A. B. *et al*: Butorphanol and Pentazocine in Patients with Severe Postoperative Pain. *Clin. Pharmacol. Ther.* 18:547-553, 1975.
- 3 Gilbert, M.S. *et al*: Intramuscular Butorphanol and Meperidine in Postoperative Pain. *Clin. Pharmacol. Ther.* 20:359-364, 1976.
- 4 Cavanagh, R.L. *et al*: Antitussive Properties of Butorphanol. *Arch. Int. Pharmacodyn. Ther.* 220: 258-268, 1976.
- 5 Shung, J.E. *et al*: Effect of Butorphanol and Morphine on Pulmonary Mechanics, Arterial Blood Pressure, and Venous Plasma Histamine in the Anesthetized Dog. *Arch. Int. Pharmacodyn. Ther.* 233:296-304, 1978.
- 6 Nagashima, H. *et al*: Respiratory and Circulatory Effects of Intravenous Butorphanol and Morphine. *Clin. Pharmacol. Ther.* 19:735-745, 1976.

NDC 0886-2033-20

Torbugesic® **IV**

BUTORPHANOL TARTRATE

FOR USE IN HORSES ONLY
NOT FOR USE IN HORSES INTENDED
FOR FOOD

READ PACKAGE INSERT

Each mL of solution contains:
Butorphanol base as
Butorphanol tartrate, USP ----- 10 mg
Calcic acid, USP ----- 3.3 mg
Sodium chloride, USP ----- 6.4 mg
Sodium chloride, USP ----- 4.7 mg
Benzethonium chloride, USP ----- 0.1 mg
Water for Injection, USP ----- q.s.
Store at controlled room temperature
15° to 30°C (59° to 86°F).

FAST GOOD

Veterinary Injection

contains 10 mg butorphanol base
per mL as butorphanol tartrate
50 mL

CAUTION: Federal law prohibits this drug
to use by or on the order of a licensed
veterinarian.

NADA 136-780, Approved by FDA

DOSAGE: By intravenous injection, 0.1
mg/kg body weight (0.05 mg/lb). This is
equivalent to 5 mL for each 1000 lb of
body weight. Dose may be repeated
within 3 to 4 hours. Treatment should
not exceed 48 hours.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

454453
LOGO

US DM

4542H
00426



Torbugesic® IV
BUTORPHANOL TARTRATE

NDC 0856-2033-20

Torbugesic® IV
BUTORPHANOL TARTRATE

FOR USE IN HORSES ONLY
NOT FOR USE IN HORSES INTENDED
FOR FOOD

FORT DODGE®

FORT DODGE®

FORT DODGE®

FORT DODGE®

See bottom flap for lot number and
expiration date.



Each mL of solution contains:
Butorphanol base as
butorphanol tartrate, USP .. 10 mg
Citric acid, USP..... 3.3 mg
Sodium citrate, USP..... 6.4 mg
Sodium chloride, USP..... 4.7 mg
Benzethonium
chloride, USP..... 0.1 mg
Water for injection, USP..... q.s.
Store at controlled room temperature
15° to 30°C (59° to 86°F).

9836
01790
4545A
9836
4545A

Veterinary Injection

contains 10 mg
butorphanol base per mL
as butorphanol tartrate

50 mL

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

NADA 135-760, Approved by FDA



READ PACKAGE INSERT

DOSAGE: By intravenous injection,
0.1 mg/kg body weight (0.05 mg/lb).
This is equivalent to 5 mL for each
1000 lbs of body weight. Dose may
be repeated within 3 to 4 hours.
Treatment should not exceed 48
hours.

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

3





Torbugesic®
BUTORPHANOL TARTRATE
 Veterinary Injection



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 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 mg/kg dosages of butorphanol resulted only in transient sedative effects. During the 10-day course of administration at 1 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 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

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

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CAUTION

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

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ADVERSE REACTIONS

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DOSAGE

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 TORBUGESIC 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 TORBUGESIC are seen within 15 minutes following injection and persist for about 4 hours.

HOW SUPPLIED

50 mL vials TORBUGESIC (butorphanol tartrate) Veterinary Injection, 10 mg base activity per mL.
 NDC 0856-2033-20 — 50 mL — vials
 10 mL vials TORBUGESIC (butorphanol tartrate) Veterinary Injection, 10 mg base activity per mL.
 NDC 0856-2033-10 — 10 mL — vials
 Store at controlled room temperature 15° to 30°C (59° to 88°F).

REFERENCES

- Pircio, A.W. et al: "The Pharmacology of Butorphanol." *Arch. Int. Pharmacodyn. Ther.* 220 (2): 231-257, 1976.
- Dobkin, A.B. et al: "Butorphanol and Pentazocine in Patients with Severe Postoperative Pain." *Clin. Pharmacol. Ther.* 18: 547-553, 1975.
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- Schurig, J.E. et al: "Effect of Butorphanol and Morphine on Pulmonary Mechanics, Arterial Blood Pressure, and Venous Plasma Histamine in the Anesthetized Dog." *Arch. Int. Pharmacodyn. Ther.* 233: 296-304, 1978.
- Nagashima, H. et al: "Respiratory and Circulatory Effects of Intravenous Butorphanol and Morphine." *Clin. Pharmacol. Ther.* 19: 735-745, 1976.
- Popio, K.A. et al: "Hemodynamic and Respiratory Effects of Morphine and Butorphanol." *Clin. Pharmacol. Ther.* 23: 281-287, 1978.
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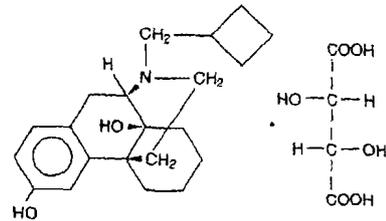
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Chemical Structure



Each mL of TORBUGESIC contains 10 mg butorphanol base (as butorphanol tartrate, USP), 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

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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.

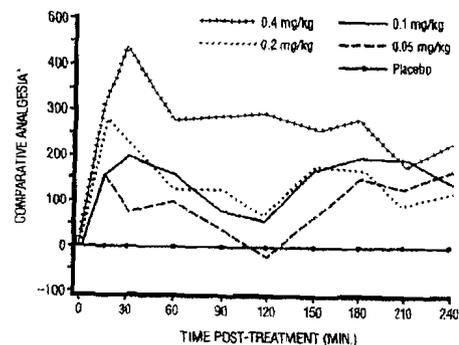
Equine Pharmacology

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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 4 hours, as illustrated in the following figure:

Analgesic Effects of Butorphanol Given at Various Dosages in Horses with Abdominal Pain



*Pain threshold in butorphanol-treated colicky horses relative to placebo controls.

Fort Dodge Animal Health
 Fort Dodge, Iowa 50501 USA