Torbutrol® (butorphanol tartrate) Veterinary Injection and Tablets

CAUTION

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

DESCRIPTION

TORBUTROL (butorphanol tartrate) is a narcotic antagonist analgesic with potent antitussive activity. It is a member of the phenanthrene series. The chemical name is hexahydro-(4H)-10, 4a-iminoethanophenanthrene tartrate (1:1). It is a white, crystalline, odorless, water soluble substance having a molecular weight of 477.66, and its molecular formula is C21H29NO2•C4H6O6.

Chemical Structure

![Chemical Structure of Torbutrol](image)

CLINICAL PHARMACOLOGY

In dogs, the antitussive properties of butorphanol given s.c. were four times more potent than morphine, 10 times more potent than pentazocine (Talwin®), and 100 times more potent than codeine. Orally butorphanol is approximately 15 to 20 times more active than either codeine or dextropropoxyphene (Diaz-McNeil). Butorphanol given intravenously in large doses (3 mg/kg) to dogs temporarily reduced arterial blood pressure. Arterial pressure returned to baseline control values within 15 to 30 minutes. Changes in cardiac contractile force and cardiac rate were of the same magnitude as the changes in arterial pressure. No appreciable effect on expired carbon dioxide was noted. No appreciable effect on arterial blood pressure was noted in studies for anesthetized dogs at equipotent doses. It has been indicated that butorphanol has less potential than morphine for causing arrhythmia, constriction, hypotension and histamine release. In conscious dogs butorphanol produced minimal cardiovascular and respiratory effects.

The specific site of action of butorphanol is not known. Butorphanol probably exerts antitussive and antinociceptive effects via the central nervous system (subcortical, possibly the hypothalamus).

INDICATIONS

TORBUTROL is indicated for the relief of chronic non-productive cough associated with tracheobronchitis, tracheitis, cough, it should not be used in conditions of the lower respiratory tract associated with copious mucus production. It is usually well tolerated when used as directed.

CONTRAINDICATIONS

1. The safety of TORBUTROL has not been determined in dogs affected with heartburn disease (Zollinger-Ellison syndrome).
2. TORBUTROL should not be used in dogs with a history of liver disease.
3. Since TORBUTROL can be effective in totally suppressing cough, it should not be used in conditions of the lower respiratory tract associated with croupous mucus production.

WARNING

FOR USE IN DOGS ONLY.

PRECAUTIONS

1. TORBUTROL has been shown to have potent analgesic activity in rodents; it is undesirable to administer other sedative or analgesic drugs during treatment with TORBUTROL, (butorphanol tartrate) as these are likely to produce an additive effect.
2. Reproduction studies, performed in mice and rabbits, revealed no evidence of impaired fertility or harm to the fetus due to butorphanol tartrate. In the rat species the female, on parenteral administration, showed 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. There are no well-controlled studies in pregnant bitches but, although there is no well-defined risk, the use of TORBUTROL in pregnant bitches is not recommended.
3. Cough suppression may be accompanied by mild sedation; the degree of sedation is dose related. If sedation is considered undesirable or unnecessary, the dose should be reduced.
4. Toxicity studies indicate that the LD50 in dogs by oral administration is greater than 50 mg/kg. In studies of 4.5 and 13 weeks duration, the following effects were noted in some but not all dogs: 4.6 times the recommended therapeutic dose level 80 mg/kg given parenterally. Increased activity, weight loss, salivation elevated SGPT and/or SAP and mild proliferative changes of the bile duct epithelium.

ADVERSE REACTIONS

The most frequent adverse reaction reported in 264 dogs treated with oral TORBUTROL was slight sedation in 6 dogs (2.3%). Other less frequent adverse reactions which have been reported include anorexia, nausea, diarrhea, and vomiting. In well-controlled studies in pregnant bitches, although vomiting was seen only in the rat species. There are no well-controlled studies in pregnant bitches, but although there is no well-defined risk, the use of TORBUTROL in pregnant bitches is not recommended.

DOSEAGE

The usual parenteral dose of TORBUTROL is 0.025 mg of butorphanol base activity per lb of body weight. This is the equivalent of 1/2 mL (0.5 mL) for each 10 lb of body weight. It should be administered slowly subcutaneously, and repeated at intervals of 6 to 12 hours as required. If necessary, the dose may be increased to a maximum of 0.05 mg/lb or 1/4 mL/10 lb of body weight. Treatment should not normally be increased for longer than seven days.

10 mL vials of TORBUTROL (butorphanol tartrate) Veterinary Injection, 0.5 mg base activity per mL.

Bottles of 100 TORBUTROL (butorphanol tartrate) Veterinary Tablets — 0.5 mg base activity per tablet.

Bottles of 100 TORBUTROL (butorphanol tartrate) Veterinary Tablets — 1 mg base activity per tablet.

Bottles of 100 TORBUTROL (butorphanol tartrate) Veterinary Tablets — 5 mg base activity per tablet.

Bottles of 100 TORBUTROL (butorphanol tartrate) Veterinary Tablets — 10 mg base activity per tablet.

Store at controlled room temperature 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F).

REFERENCES


Zogis

Distributed by Zogis Inc.
Kalamazoo, MI 49007

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Zogis / This copy of the document was retrieved from the system by Michaella Braskie on 30 Apr 2018 (UTC).
The specific site of action of butorphanol is not known. Butorphanol probably exerts analgesic and antitussive effects via the central nervous system (subcortical, possibly the hypothalamus).

Contraindications

1. The safety of TORBUTROL has not been determined in dogs affected with heartland disease (Dirofilaria immitis). 2. TORBUTROL should not be used in dogs with a history of liver disease.

Side Effects

Cough suppression may be accompanied by mild sedation; the degree of sedation is dose related. If sedation is consid- ered undesirable or unnecessary, the dose should be reduced.

Precautions

1. TORBUTROL has been shown to have potent analgesic activity in rodents; it is not undesirable to administer other sedative or analgesic drugs during treatment with TORBUTROL (butorphanol tartrate) as these are likely to produce an additive effect.

References


How Supplied

10 mL vials TORBUTROL (butorphanol tartrate) Veterinary Injection -0.25 mg of butorphanol base activity per mL. Bottles of 100 TORBUTROL (butorphanol tartrate) Veterinary Tablets — 1 mg base activity per tablet. Bottles of 100 TORBUTROL (butorphanol tartrate) Veterinary Tablets — 10 mg base activity per tablet. Store at controlled room temperature 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F).

Safety

Following the marketing of TORBUTROL Veterinary Injection transient sedation and ataxia have been reported rarely as side effects in dogs.

Adverse Reactions

The most frequent adverse reaction reported in 264 dogs treated with oral TORBUTROL was slight sedation in 6 dogs (2.3%). Other less frequent adverse reactions which have been reported include anorexia/nasal/oral discharge (reported incidence less than 1%).

The usual oral dose of TORBUTROL is 0.025 mg of butorphanol base activity per lb of body weight. This is the equivalent of 0.5 mL (0.5 mL) for each 10 lb of body weight. It should be administered by subcutaneous injection, and repeated at intervals of 6 to 12 hours as required. If neces- sary, the dose may be increased to a maximum of 0.05 mg or 1 mL/10 lb body weight. Treatment should not normally be required for longer than seven days.

The usual oral dose of TORBUTROL is 0.25 mg of butorphan- ol base activity per lb of body weight. This is the equivalent of one 5 mg tablet per 20 lb of body weight. The dose should be repeated at intervals of 6 to 12 hours as required. If neces- sary, the dose may be increased to a maximum of one 5 mg tablet for each 10 lb of body weight. Treatment should not normally be required for longer than seven days.

Reproduction Studies

Reproduction studies, performed in mice and rabbits, revealed no evidence of impaired fertility or harm to the fetus due to butorphanol tartrate. In the rat species, the female, on paternal administration, showed increased nervousness and decreased care for the newborns, resulting in a decreased survival rate of the newborns. This nor-