**Torbutrol®**

**Butorphanol Tartrate**

**Veterinary Injection and Tablets**

### CLINICAL PHARMACOLOGY

In dogs, the antinociceptive properties of butorphanol given s.c. were four times more potent than meperidine, 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 dexmethorphan. It is more potent than pentazocine (Talwin®), and 100 times more powerful than codeine. Butorphanol probably exerts analgesic and antitussive 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, bronchitis, sputum and pharyngitis originating from inflammatory conditions of the upper respiratory tract.

### CONTRAINDICATIONS

1. The safety of **TORBUTROL** has not been determined in dogs affected with herpesvirus infection (Canine Herpesvirus 1).

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 excessive mucous 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 anxiolytic drugs during treatment with **TORBUTROL** (butorphanol tartrate) as these are likely to produce an additive effect.

2. Reproductive 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 neonatality and decreased care for the infant, resulting in a decreased survival rate of the neonates. This neonatality 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. Toxicology 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 of dogs at 4.5 times the recommended therapeutic dose level BID given parenterally: Decreased activity, weight loss, ataxia, elevation in 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 may have been reported include anorexia, nausea and diarrhea (reported incidence less than 1%). Following the marketing of **TORBUTROL** Veterinary Injection treatment sedation and ataxia have been reported rarely as side effects in dogs.

### DOSAGE

The usual parenteral dose of **TORBUTROL** is 0.025 mg of butorphanol base activity per lb of body weight. This is the equivalent of 0.25 mg for each 15 lbs of body weight. It should be administered by subcutaneous injection, 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 mg/70 lbs body weight. Treatment should not normally be required for longer than seven days.

The usual dose of **TORBUTROL** is 0.025 mg of butorphanol base activity per lb of body weight. This is the equivalent of 0.5 mg/mL for each 15 lbs of body weight. It should be administered by subcutaneous injection, 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 mg/70 lbs body weight. Treatment should not normally be required for longer than seven days.

### HOW SUPPLIED

10 ml vials **TORBUTROL** (butorphanol tartrate) Veterinary Injection, 0.05 mg per mL basic activity.

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

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

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

Store at controlled room temperature 20°-25°C (68°-77°F). With excursions between 15°-30°C (59°-86°F). Distributed by Zoetis Inc, Kalamazoo, MI 49007

Revised: October 2013

### REFERENCES


### CAUTION

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

**DESCRIPTION**

**TORBUTROL** (butorphanol tartrate) is a narcotic agonist-antagonist analgesic with potent antitussive activity. It is a member of the phenanthrene series. The chemical name is levorotatory (α-levo-N-cyclobutylmethyl-6,10-tetrahydro-5H-dibenzo[a,d][1,4]xanthene). It is a white, crystalline, water soluble substance having a molecular weight of 477.56, and its molecular formula is C₂₃H₂₃NO₂·C₄H₆O₆.

**Chemical Structure**

![Chemical Structure](image-url)

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### Dimensions

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