

Torphasol 10mg/ml Solution for Injection for Horses

Introduction



Company name: Animalcare Limited
Address: **Common Road**
Dunnington
York YO19 5RU
Telephone: **01904 487687**
Fax: **01904 487611**
Email: animalcare@animalcare.co.uk

Presentation

A clear, colourless solution for injection containing 10mg/ml butorphanol (as butorphanol tartrate). Also contains chlorocresol 1mg/ml as preservative.

Uses

For the short-term relief of pain associated with colic of gastrointestinal tract origin. For sedation in combination with certain alpha-2 adrenoceptor agonists.

Dosage and administration

For intravenous administration only.

For analgesia: Dose rate: 100µg/kg butorphanol (equivalent to 1ml per 100kg), by intravenous injection. Butorphanol is intended for use where short duration analgesia is required. The dose may be repeated as required. The need for and timing of repeat treatment will be based on clinical response. For cases where longer duration analgesia is likely to be required, an alternative therapeutic agent should be used.

For sedation in combination with detomidine hydrochloride: A dose rate of 12µg/kg detomidine hydrochloride should be given intravenously followed within 5 minutes by a dose rate of 25µg/kg butorphanol (equivalent to 0.25ml per 100kg) intravenously.

For sedation in combination with romifidine: A dose of 40 – 120µg/kg romifidine followed within 5 minutes by a dose rate of 20µg/kg butorphanol (equivalent to 0.2ml per 100kg) should be administered intravenously.

For sedation in combination with xylazine: A dose rate of 500µg/kg xylazine followed immediately by a dose of 25 – 50µg/kg butorphanol (equivalent to 0.25 – 0.5ml per 100kg) should be administered intravenously.

Contra-indications, warnings, etc

Butorphanol as a sole agent and in any combination: Do not use in horses with a history of liver or kidney disease.

Butorphanol/detomidine hydrochloride combination: The combination should not be used in pregnant animals. Do not use the combination in horses with a pre-existing cardiac dysrhythmia or bradycardia.

Butorphanol/romifidine combination: Do not use during the last month of pregnancy.

Butorphanol/xylazine combination: The combination should not be used in pregnant animals.

Any reduction in gastrointestinal motility caused by butorphanol may be enhanced by the concomitant use of alpha-2 adrenoceptor agonists. Consequently, such combinations should not be used in cases of colic associated with impaction.

Adverse reactions: Butorphanol may cause the following side-effects: excitatory locomotor effects (pacing), mild sedation (may occur following the administration of butorphanol as a sole agent), ataxia, reduction in gastrointestinal motility and depression of the cardiovascular system.

Special warnings: Safety and efficacy of butorphanol in foals have not been established. In foals use the product only according to the benefit/risk assessment by the responsible veterinarian. Due to its antitussive properties, butorphanol may lead to an accumulation of mucus in the respiratory tract. Therefore, in animals with respiratory diseases associated with increased mucus production or in animals that are being treated with expectorants, butorphanol should only be used on the basis of a risk-benefit analysis by the responsible veterinarian. The use of the product at the recommended dose may lead to transient ataxia and/or excitement. Therefore, to prevent injuries in patient and people, the location for the treatment should be chosen carefully.

Butorphanol may be used in combination with other sedatives such as alpha-2 adrenoceptor agonists (e.g. romifidine, detomidine, xylazine) where synergistic effects can be expected. Therefore, an appropriate reduction in dose is necessary when used concomitantly with such agents. Because of its antagonist properties at the opiate mu receptor, butorphanol may inhibit the analgesic effect in animals, which have already received pure opioid mu agonists (morphine/oxymorphone).

Butorphanol/detomidine hydrochloride combination: Routine cardiac auscultation should be performed prior to use in combination with detomidine.

Use during pregnancy and lactation: The safety of this product has not been investigated in the target species during pregnancy and lactation. The use of butorphanol during pregnancy and lactation is not recommended.

Overdose: The main sign of overdose is respiratory depression which can be reversed with an opioid antagonist (naloxone). Other possible signs of overdose in the horse include restlessness/excitability, muscle tremor, ataxia, hypersalivation, decrease of gastrointestinal motility and seizure.

Withdrawal periods: Meat and offal: Zero days, Milk: Zero hours

User warnings: Direct contact with skin or eyes of the user should be avoided since the product might induce irritation and sensitization. Accidental spillage on the skin should be washed immediately with soap and water. When the product comes in contact with eyes, rinse immediately with plenty of water. Care should be taken when handling the product to avoid accidental self-injection. In case of accidental self injection, seek medical advice immediately and show the package insert or the label to the physician, and do not drive since drowsiness, nausea and dizziness may occur. Effects can be reversed by the administration of an opioid antagonist.

Pharmaceutical precautions

For animal treatment only. Keep the container in the outer carton. Keep out of the reach and sight of children. Do not use after the expiry date stated on the carton and vial after Exp.. Shelf-life after first opening the vial: 28 days.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Disposal: Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Legal category

POM-V

Packaging Quantities

20ml clear glass vials

Further information

Nil

Marketing Authorisation Holder (if different from distributor)

Animedica GmbH, Germany

Marketing authorisation number

Vm 24745/4009.

Significant Changes