

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torphasol 10 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Butorphanol 10 mg
(as Butorphanol tartrate 14.7 mg/ml)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzethonium chloride	0.1 mg
Citric acid monohydrate	
Sodium citrate	
Sodium chloride	
Water for injections	

A clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For short term relief of pain associated with colic of gastrointestinal tract origin.

For sedation in combination with certain α_2 -adrenoceptor agonists.

3.3 Contraindications

Butorphanol – as a sole agent and in any combination:

Do not use in horses with a history of liver or kidney disease.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cases of cerebral injury or organic brain lesions (e.g. lesions following cranial trauma) and in animals with obstructive respiratory diseases, heart dysfunction or spastic convulsions.

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.

Do not use in horses with emphysema due to a possible depressive effect in the respiratory system.

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 α_2 -adrenoceptor agonists. Consequently, such combinations should not be used in cases of colic associated with impaction.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Safety and efficacy of butorphanol in foals have not been established. In foals, use the veterinary medicinal product only according to the benefit/risk assessment by the responsible veterinarian.

Due to its antitussive properties, butorphanol may lead to an accumulation of mucous in the respiratory tract. Therefore, in animals with respiratory diseases associated with increased mucous 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 veterinary medicinal 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 / detomidine hydrochloride combination:

Routine cardiac auscultation should be performed prior to use in combination with detomidine.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Direct contact with skin or eye of the user should be avoided since the veterinary medicinal product might induce irritation and sensitization. Accidental spillage on the skin should be washed immediately with soap and water. When the veterinary medicinal product comes into contact with the eyes, rinse immediately with plenty of water.

Care should be taken when handling the veterinary medicinal product to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data):	Ataxia Sedation ¹ Pacing ² Digestive tract hypomotility
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Cardiac depression

¹ Mild and may occur following the administration of butorphanol as a sole agent.

² Excitatory locomotor effects.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use of butorphanol during pregnancy and lactation is not recommended.

3.8 Interaction with other medicinal products and other forms of interaction

Butorphanol may be used in combination with other sedatives such as α 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).

Because of the antitussive properties of butorphanol, it should not be used in combination with an expectorant, as this may lead to an accumulation of mucous in the airways.

The combination of butorphanol and α 2-adrenoceptor agonists should be used with caution in animals with cardiovascular disease. The concurrent use of anticholinergic drugs, e.g. atropine should be considered.

3.9 Administration routes and dosage

Intravenous use.

Analgesia:

Dose rate: 100 μ g butorphanol per kg bodyweight (BW) (equivalent to 1 ml for 100 kg BW), 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.

Sedation in combination with detomidine hydrochloride:

A dose rate of 12 μ g detomidine hydrochloride per kg BW should be given intravenously followed within 5 minutes by a dose rate of 25 μ g butorphanol per kg BW (equivalent to 0.25 ml for 100 kg BW) intravenously.

Sedation in combination with romifidine:

A dose of 40-120 μ g romifidine per kg BW followed within 5 minutes by a dose rate of 20 μ g butorphanol per kg BW (equivalent to 0.2 ml for 100 kg BW) should be administered intravenously.

Sedation in combination with xylazine:

A dose rate of 500 μ g xylazine per kg BW followed immediately by a dose of 25-50 μ g butorphanol per kg BW (equivalent to 0.25-0.5 ml per 100 kg) should be administered intravenously.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero days.

Milk: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QN02AF01

4.2 Pharmacodynamics

Butorphanol tartrate is a centrally acting analgesic. Its action is agonist-antagonist at the opiate receptors in the central nervous system; agonist at the kappa opioid receptor subtype and antagonist at the mu receptor subtype. The kappa receptors control analgesia, sedation without depression of cardiopulmonary system and body temperature, whereas the mu receptors control supraspinal analgesia, sedation and depression of cardiopulmonary system and body temperature. The agonist component of butorphanol activity is ten times more potent than the antagonist component.

Onset and duration of analgesia:

Analgesia generally occurs within 15 minutes following intravenous administration. After a single intravenous dose in the horse, analgesia usually lasts for 15-90 minutes.

4.3 Pharmacokinetics

Following intravenous injection, butorphanol is well distributed in tissue. Butorphanol is metabolised extensively in the liver and excreted in the urine. In horses, butorphanol administered by intravenous route has a high clearance (21 ml/kg/min) and a short terminal half-life (44 minutes), indicating that 97% of a dose will be eliminated after intravenous administration in, on average, less than 5 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 clear glass vial (type I) of 20 ml with a grey butyl rubber stopper and an aluminium cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/009/001

8. DATE OF FIRST AUTHORISATION

29/10/2010

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

08/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).