1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Morphasol 4 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Butorphanol 4 mg
(as Butorphanol tartrate 5.83 mg)

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

Dogs and cats.

3.2 Indications for use for each target species

Dogs:
As an analgesic: for the relief of mild to moderate visceral pain.
As a sedative: in combination with medetomidine.

Cats:
As an analgesic: for the relief of mild to moderate visceral pain.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with known or suspected liver or kidney disease.
Use of butorphanol is contraindicated in case of cerebral injury or organic brain lesions and in animals with obstructive respiratory diseases, heart dysfunction or spastic conditions.

3.4 Special warnings

Butorphanol is intended for use where short (dog) and short to medium (cat) analgesia is required. For information on the duration of analgesia that can be expected following treatment, see section 4.2.

However, repeat treatments of butorphanol may be administered. For cases where longer duration analgesia is likely to be required, an alternative therapeutic agent should be used.
The safety of the veterinary medicinal product in young puppies and kittens has not been established. Use of the veterinary medicinal product in these groups should be on the basis of a benefit: risk analysis by the responsible veterinarian.
In cats, individual response to butorphanol may be variable. In the absence of an adequate analgesic response, an alternative analgesic agent should be used.
In cats, increasing the dose may not increase the intensity or duration of analgesia.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Routine cardiac auscultation should be performed prior to use in combination with α_2-adrenoceptor agonists. 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. In cases of respiratory depression, it can be reversed by an opioid antagonist (e.g. Naloxone).
Sedation may be noted in treated animals.
Due to the antitussive properties of butorphanol, it should not be used in combination with an expectorant or in animals with respiratory disease associated with increased mucous production, as this may lead to accumulation of mucous in the airways.
Cats should be weighed to ensure that the correct dose is calculated. Use of either insulin syringes or 1 ml graduated syringes is recommended.

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. Care should be taken when handling the veterinary medicinal product to avoid self-injection. 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. 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

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Ataxia[1] Anorexia[1] Diarrhoea[1]
Undetermined frequency (cannot be estimated from the available data):	Cardiac depression Respiratory depression Digestive tract hypomotility Sedation[2]

[1] Transient.
[2] Mild.

Cats:

Undetermined frequency (cannot be estimated from the available data):	Cardiac depression Respiratory depression Mydriasis Disorientation Agitation Anxiety Restlessness Increased sensitivity to sound Sedation[1]

[1] Mild.

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 is not recommended during pregnancy and lactation.

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. medetomidine in dogs) where synergistic effects can be expected. Therefore, an appropriate reduction in dose is necessary when used concomitantly with such agents (see section 3.9).
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 concomitant use of α_2-agonists may decrease gastrointestinal motility.
Because of its antagonist properties at the opiate mu (μ) receptor butorphanol may remove the analgesic effect in animals, which have already received pure opioid mu (μ) agonists (morphine/oxymorphine).

3.9 Administration routes and dosage

Intravenous use.

Dogs:
Analgesia:
intravenous administration of 0.2 - 0.4 mg/kg bodyweight (BW) butorphanol (equivalent to 0.05 - 0.1 ml/kg BW). For postoperative analgesia intravenous administration of 0.2 - 0.4 mg/kg BW butorphanol is recommended 20 minutes prior to end of soft tissue surgery.
Sedation in combination with medetomidine:
intravenous administration of 0.1 - 0.2 mg/kg BW butorphanol (equivalent to 0.025 - 0.05 ml/kg BW) with 10 - 30 μg/kg BW medetomidine, depending on degree of sedation required.

Cats:
Analgesia:
intravenous administration of 0.1-0.2 mg/kg BW butorphanol (equivalent to 0.025-0.05 ml/kg BW)

Avoid rapid intravenous injection.

Butorphanol is intended for use where short (dog) and short to medium (cat) analgesia is required. For information on the duration of analgesia that can be expected following treatment, see section 4.2. However, repeat treatments of butorphanol may be administered. The need for, and timing of repeat treatment should be based on clinical response. For cases where longer duration analgesia is likely to be required, an alternative therapeutic agent should be used.

In the absence of an adequate analgesic response (see section 3.4), use of an alternative analgesic agent, such as another suitable opioid analgesic and/or a non-steroidal anti-inflammatory drug, should be considered. Any alternative analgesia should take account of the action of butorphanol on opioid receptors, as described in Section 3.8.

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 (e.g. Naloxone).

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QN02AF01

4.2 Pharmacodynamics

Butorphanol tartrate is a synthetic opioid, with agonist - antagonist action at the opiate receptors in the central nervous system. It possesses agonist activity at the kappa receptor subtype which control analgesia, sedation without depression of the cardiopulmonary system or body temperature. It has antagonist activity at the mu receptor subtype which controls analgesia, sedation, depression of the cardiovascular system and body temperature. It also possesses weak affinity to the δ-receptors, which may occasionally cause dysphoria.
The agonist component is ten times more potent than the antagonist component.
The analgesic effect of butorphanol occurs within 15 minutes following intravenous administration in dogs and cats and lasts from 15 minutes up to 30 minutes in dogs. The duration of effect lasts for 15 minutes up to 6 hours in cats. Duration of effect in cats relates to visceral pain only. In cats with somatic pain the duration of effect is likely to be considerably shorter.

4.3 Pharmacokinetics

The volume of distribution after intravenous injection is large (7.4 l/kg for cats and 4.4 l/kg for dogs) suggesting wide distribution into tissues. The terminal half-life of butorphanol is short: 4.1 hours for cats and 1.7 hours for dogs. Butorphanol is metabolised extensively in the liver and mainly excreted in urine.

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

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 glass vial (type I) of 10 ml with a grey butyl rubber stopper and an aluminium cap.
Cardboard box with 5 glass vials (type I) of 10 ml with grey butyl rubber stopper and an aluminium cap.

Not all pack sizes may be marketed.

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)

VPA10826/007/001

8. DATE OF FIRST AUTHORISATION

18/12/2009

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

20/06/2025

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).