SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ButorVet 10 mg/ml Solution for Injection for horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Butorphanol 10 mg/ml
(as butorphanol tartrate 14.58 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	

Clear, colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Horse, dog and cat.

3.2 Indications for use for each target species

Horse

As an analgesic:
For the relief of moderate to severe abdominal pain associated with colic of gastrointestinal origin.

As a sedative:
For sedation, given after the administration of certain alpha2-adrenoceptor agonists (detomidine, romifidine)

Dog

As an analgesic:
For the relief of moderate visceral pain in dogs.

As a sedative:
For sedation in conjunction with certain alpha2-adrenoceptor agonists (medetomidine)

As a premedicant prior to general anaesthesia:
For use as a premedicant as a sole agent or in combination with acepromazine. A dose-related reduction in the dose of induction-anaesthetic agent (propofol) is also provided.

As an anaesthetic:
For anaesthesia when used in combination with medetomidine and ketamine.

Cat

As an analgesic for the relief of moderate pain:
For pre-operative use to provide analgesia during surgery.
For post-operative analgesia after small surgical procedures.

As a sedative:
For sedation when used in combination with certain alpha2-adrenoceptor agonists (medetomidine).

As an anaesthetic:
For anaesthesia, when used in combination with medetomidine and ketamine, suitable for short painful anaesthetic procedures.

3.3 Contraindications

All target species:
Do not use in known cases of hypersensitivity to the active substance or any of the excipients.
Do not use in animals with severe dysfunction of the liver or kidneys.
Do not use in animals with cerebral injury or organic brain lesions.
Do not use in animals with obstructive respiratory disease, heart dysfunction or spastic conditions.

Horse:

Butorphanol/detomidine hydrochloride combination:
Do not use in cases of colic associated with impaction as the combination will cause a reduction in gastrointestinal motility.
Do not use in horses with a pre-existing cardiac dysrhythmia or bradycardia.
Do not use in horses with emphysema due to a possible depressive effect on the respiratory system.
Do not use in pregnant mares.

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

3.4 Special warnings

Butorphanol is intended for use where short duration analgesia (horse, dog) or short to medium duration analgesia (cat) is required (see section 4.2). In cases where longer duration analgesia is likely to be required, an alternative therapeutic agent should be used. Marked sedation does not occur when butorphanol injection is used as a sole agent in cats. In cats increasing the dose will not increase intensity or duration of desired effects.

3.5 Special precautions for use

Special precautions for safe use in the target species:
All target species:
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, butorphanol should only be used according to a benefit-risk assessment by the responsible veterinary surgeon.
Prior to use of the product in combination with α2-adrenoreceptor agonists routine cardiac auscultation should be performed and the concurrent use of anticholinergic drugs, e.g. atropine should be considered.
The combination of butorphanol and an α2-adrenoceptor agonists should be used with caution in animals with mild to moderate dysfunction of the liver or kidney.
Take care when administering butorphanol to animals concurrently treated with other central nervous depressants (see section 3.8).
The safety of the product in puppies, kittens and foals has not been established and therefore in these animals the product should only be used according to a benefit-risk assessment by the responsible veterinary surgeon.

Horse
The use of the product at the recommended dose may lead to transient ataxia and/or excitement. Therefore, to prevent injuries, in the patient and people when treating horses, the location for the treatment should be chosen carefully.

Dog
When administering as an intravenous injection, do not inject as a bolus.
In dogs with MDR1 mutation reduce dose by 25-50%.

Cat
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
Butorphanol has opioid-like activity. The most frequent adverse effects of butorphanol in humans are drowsiness, sweating, nausea, dizziness, and vertigo and these may occur following unintended self-injection. Care should be taken to avoid accidental injection/self-injection. If accidental self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive. An opioid antagonist (e.g. naloxone) may be used as an antidote.

Wash splashes from skin and eyes immediately.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Ataxia[1,2], Sedation[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[4] Digestive tract disorder[5] Pacing[6] Cardiac depression[7]

[1] Mild; may persist for 3 to 10 minutes.
[2] Mild to severe ataxia may be encountered in combination with detomidine, but clinical studies have shown that horses are unlikely to collapse. Normal precautions should be observed to prevent self-injury.
[3] Following the administration of the product as a sole agent, may occur in approximately 15% of horses
[4] Following intramuscular injection.
[5] May also have adverse effects on gastrointestinal tract motility in horses, although there is no decrease in gastrointestinal transit time. These effects are dose-related and generally minor and transient.
[6] May cause excitatory locomotor effects.
[7] When used in combination with α2-adrenoceptor agonists, cardiopulmonary system depression may occur very rarely. In these cases, fatality may occur rarely.

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anorexia[8] Ataxia[8] Diarrhoea[8]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[9] Respiratory depression[10] Cardiac depression[10] Digestive tract disorder[11]

[8] Transient
[9] Following intramuscular injection.
[10] A decrease in respiratory rate, development of bradycardia and a decrease in diastolic pressure may occur. The degree of depression is dose dependent.
[11] Reduction in gastrointestinal motility

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[12] Excitation Dysphoria Mydriasis Respiratory depression

[12] Following intramuscular injection.

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

The safety of this veterinary medicinal product has not been established in the target species during pregnancy and lactation. The use of butorphanol during pregnancy and lactation is not recommended. See also section 3.3.

3.8 Interaction with other medicinal products and other forms of interaction

When butorphanol is used in combination with certain α2-adrenoceptor agonists (romifidine or detomidine in horses, medetomidine in dogs and cats) synergistic effects occur requiring a butorphanol dose reduction (see section 3.5 and 3.9).
Butorphanol is antitussive and should not be used in combination with an expectorant as it may lead to an accumulation of mucous in the airways.
Butorphanol has antagonist properties at the opiate mu (μ) receptor which may remove the analgesic effect of pure opioid mu (μ) agonists (e.g. morphine/oxymorphine) in animals that have already received these agents.
The concomitant use of other central nervous depressants would be expected to potentiate the effects of butorphanol and such drugs should be used with caution. A reduced butorphanol dose should be used when administering these agents concurrently.

3.9 Administration routes and dosage

The closures should not be punctured more than 30 times.

Horse

For analgesia:

Route	Dose butorphanol	**Dose product**
IV	0.10 mg/kg bw	**1 ml/100 kg bw**
Comment	Analgesic effects are seen within 15 minutes of injection. Dose may be repeated as required.	

For sedation in combination with detomidine hydrochloride:

Route	Dose of detomidine hydrochloride	Dose butorphanol*	**Dose product**
IV	0.012 mg/kg bw	0.025 mg/kg bw	**0.25 ml/100 kg bw**
Comment	Detomidine should be administered up to 5 minutes before the butorphanol dose.		

*Clinical experience has shown that a total dose rate of 5 mg detomidine hydrochloride and 10 mg butorphanol affords effective, safe sedation in horses above 200 kg body weight.

For sedation in combination with romifidine:

Route	Dose of romifidine	Dose butorphanol	**Dose product**
IV	0.04-0.12 mg/kg bw	0.02 mg/kg bw	**0.2 ml/100 kg bw**
Comment	Romifidine should be administered up to 5 minutes before the butorphanol dose.		

Dog

For analgesia:

Route	Dose butorphanol	**Dose product**
IV,IM or SC	0.20-0.30 mg/kg bw	**0.02-0.03 ml/kg bw**
Comment	IV injection should be slow. Analgesic effects are seen within 15 minutes of injection. Administer 15 minutes before terminating anaesthesia to provide analgesia in the recovery phase. For continuous analgesia repeat dose as required.	

For sedation in combination with medetomidine hydrochloride:

Route	Dose butorphanol	**Dose product**	Dose medetomidine
IM or IV	0.1 mg/kg bw	**0.01 ml/kg bw**	0.01-0.025 mg/kg bw
Comment	Allow 20 minutes for profound sedation to develop before commencing the procedure. Where compatibility is accepted, products containing medetomidine and butorphanol may be combined and administered in the same syringe (see section 5.1). The medetomidine dose should be adjusted depending on the depth of sedation required.		

For use as a premedicant:

- When the product is used as the sole agent:

Route	Dose butorphanol	**Dose product**
IV, IM or SC	0.1-0.20 mg/kg bw	**0.01-0.02 ml/kg bw**
Comment	15 minutes prior to induction	

- When the product is used together with 0.02 mg/kg acepromazine:

Route	Dose butorphanol	**Dose product**
IV or IM	0.10 mg/kg bw*	**0.01 ml/kg bw***
Comment	Allow at least 20 minutes before the onset of action but the time between pre-medication and induction is flexible from 20-120 minutes. Where compatibility is accepted, products containing butorphanol and acepromazine may be combined and administered in the same syringe (see section 5.1).	

* The dose may be increased to 0.2 mg/kg (equivalent to 0.02 ml/kg) if the animal is already experiencing pain before the procedure commences or if a higher plane of analgesia is required during surgery.

For anaesthesia in combination with medetomidine and ketamine:

Route	Dose butorphanol	**Dose product**	Dose medetomidine	Dose ketamine
IM	0.10 mg/kg bw	**0.01 ml/kg bw**	0.025mg/kg bw	5.0mg/kg bw
Comment	**Reversal with atipamezole is not recommended** Where compatibility is accepted, products containing medetomidine and butorphanol may be combined and administered in the same syringe (see section 5.1). Ketamine should be administered 15 minutes after the IM administration of the butorphanol/medetomidine combination.			

Cat

For pre-operative analgesia:

Route	Dose butorphanol	**Dose product**
IM or SC	0.4 mg/kg bw	**0.04 ml/kg bw**
Comment	Administer 15-30 minutes prior to the administration of IV induction anaesthetic agents Administer 5 minutes before induction with IM induction anaesthetic agents such as combinations of IM acepromazine/ ketamine or xylazine/ketamine	

For post-operative analgesia:

Route	Dose butorphanol	**Dose product**
SC or IM	0.4 mg/kg bw	**0.04 ml /kg bw**
IV	0.1 mg/kg bw	**0.01 ml /kg bw**
Comment	Administer 15 minutes before recovery	

For sedation in combination with medetomidine hydrochloride:

Route	Dose butorphanol	**Dose product**	Dose medetomidine hydrochloride
IM or SC	0.4 mg/kg bw	**0.04 ml/kg bw**	0.05 mg/kg bw
Comment	Local anaesthetic infiltration should be used for wound suturing. Where compatibility is accepted, products containing medetomidine and butorphanol may be combined and administered in the same syringe (see section 5.1).		

For anaesthesia in combination with medetomidine and ketamine:

Route	Dose butorphanol	**Dose product**	Dose medetomidine	Dose ketamine
IM	0.40 mg/kg bw	**0.04 ml/kg bw**	0.08 mg/kg bw	5.0 mg/kg bw*
IV	0.10 mg/kg bw	**0.01 ml/kg bw**	0.04 mg/kg bw	1.25-2.50 mg/kg bw (depending on depth of anaesthesia required)
Comment	Where compatibility is accepted, products containing medetomidine, butorphanol and ketamine may be combined and administered in the same syringe (see section 5.1).			

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 naloxone.
To reverse the sedative effect of butorphanol/alpha-2 adrenoceptor agonist combinations, atipamezole may be used. To reverse adverse cardiopulmonary effects of these combinations, higher atipamezole doses may be required.
Atipamezole should not be used in dogs treated with a combination of butorphanol, medetomidine, and ketamine used intramuscularly to produce anaesthesia.
Other possible signs of overdose in the horse include restlessness/excitability, muscle tremor, ataxia, hypersalivation, decrease of gastrointestinal motility and seizure.
In the cat, the main signs of overdose are incoordination, salivation, and mild convulsions.

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

Horse (Meat and offal): Zero days

Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QNO2AF01

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 (k) opioid receptor subtype and antagonist at the mu (μ) receptor subtype. The kappa (k) receptors control analgesia, sedation without depression of cardiopulmonary system and body temperature, whereas the mu (μ) 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 administration in horse, dog and cat. After a single intravenous dose in the horse, analgesia usually lasts for 15 – 60 minutes. In the dog, it lasts for 15 - 30 minutes after a single intravenous administration. In cats with visceral pain, analgesic effect for 15 minutes up to 6 hours after butorphanol administration has been demonstrated. In cats with somatic pain, the duration of analgesia has been considerably shorter.

4.3 Pharmacokinetics

In the horse, butorphanol has a high clearance (on average 1.3 L/h.kg) after intravenous administration. It has a short terminal half-life (mean < 1 hour), indicating that 97% of a dose will be eliminated after intravenous administration in, on average, less than 5 hours.
In the dog, butorphanol administered by the intramuscular route has a high clearance (around 3.5 L/h.kg). It has a short terminal half-life (mean < 2 hours), indicating that 97% of a dose will be eliminated after intramuscular administration in, on average, less than 10 hours. Repeated dose pharmacokinetics and the pharmacokinetics following intravenous administration have not been studied.
In the cat, butorphanol administered by the subcutaneous route has a low clearance (< 1.32 L/h.kg). It has a relatively long terminal half-life (around 6 hours) indicating that 97% of the dose will be eliminated in approximately 30 hours. Repeated dose pharmacokinetics have not been studied. Butorphanol is metabolized extensively in the liver and excreted in the urine. The volume of distribution is large, suggesting wide distribution into tissue.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

ButorVet must not be mixed with other products with the exception of the following combinations:
i) ButorVet and Domitor
ii) ButorVet, Domitor and Ketaset (where registered).
iii) ButorVet and acepromazine

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years
Shelf life after first opening the immediate packaging: 30 days

5.3 Special precautions for storage

Store below 25°C.

5.4 Nature and composition of immediate packaging

Type I clear glass multi-dose vials, with chlorobutyl rubber stoppers secured with an aluminium cap.

Package sizes:
Cardboard box containing 1 vial of 10 ml.
Cardboard box containing 1 vial of 20 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

7. MARKETING AUTHORISATION NUMBERS

Vm 40162/3004 (NI)
Vm 40162/5004 (GB)

8. DATE OF FIRST AUTHORISATION

18 February 2025

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

February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 18 March 2025