

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Butorphanol 10 mg/ml
(as butorphanol tartrate 14.58 mg/ml)

3. PACKAGE SIZE

10 ml
20 ml

4. TARGET SPECIES

Horse, dog and cat

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: Intravenous injection
Dogs/cats: intravenous, intramuscular, or subcutaneous injection

7. WITHDRAWAL PERIODS

Withdrawal period:
Horse (Meat and offal): Zero days
Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 30 days.
Once broached, use by: __

9. SPECIAL STORAGE PRECAUTIONS

Store below 25°C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 40162/5004 (GB)

Vm 40162/3004 (NI)

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {VIAL}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Butorphanol 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 30 days.

Once broached, use by.....

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Active substance

Butorphanol 10 mg/ml
(as butorphanol tartrate 14.58 mg/ml)

Solution for Injection.
Clear, colourless liquid.

3. Target species

Horse, dog and cat.

4. Indications for use

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.

5. 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.

6. Special warnings

Special warnings:

Butorphanol is intended for use where short duration analgesia (horse, dog) or short to medium duration analgesia (cat) is required. 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.

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 $\alpha 2$ -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 $\alpha 2$ -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 .

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.

Pregnancy and lactation:

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 5.

Interaction with other medicinal products and other forms of interaction:

When butorphanol is used in combination with certain α 2-adrenoceptor agonists (romifidine or detomidine in horses, medetomidine in dogs and cats) synergistic effects occur requiring a butorphanol dose reduction (see section 8).

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/oxymorphone) 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.

Overdose:

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.

Special restrictions for use and special conditions for use:

Not applicable.

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

7. 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 Gastrointestinal tract motility ⁵ Pacing ⁶ Cardiac depression ⁷

¹Mild; 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

⁴Following 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 α 2-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

⁹Following intramuscular injection.

¹⁰A decrease in respiratory rate, development of bradycardia and a decrease in diastolic pressure) may occur. The degree of depression is dose dependent.

¹¹Reduction in gastrointestinal motility

Cats:

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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 6). 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 6).	

* 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	<p>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 6). Ketamine should be administered 15 minutes after the IM administration of the butorphanol/medetomidine combination.</p>			

Cat**For pre-operative analgesia:**

Route	Dose butorphanol	Dose product
IM or SC	0.4 mg/kg bw	0.04 ml/kg bw
Comment	<p>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</p>	

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 6).		

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 6).			

9. Advice on correct administration

Not applicable.

10. Withdrawal periods

Horse (Meat and offal): Zero days

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

11. Special storage precautions

Store below 25 C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 30 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater. 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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 40162/5004 (GB)

Vm 40162/3004 (NI)

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

C&H Generics Ltd
c/o Michael McEvoy & Co.
Seville House
New Dock Street
Galway
Ireland

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

17. Other information

POM-V

Gavin Hall

Approved: 18 March 2025