PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torphadine 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Butorphanol 10.0 mg
(Equivalent to 14.58 mg of butorphanol tartrate)

3. PACKAGE SIZE

10 ml
20 ml

4. TARGET SPECIES

Dogs, cats and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dog and cat: Intravenous, intramuscular and subcutaneous use.
Horse: Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
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 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/4037

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {10, 20 ml glass vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torphadine

10 ml
20 ml

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 28 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Torphadine 10 mg/ml solution for injection for dogs, cats and horses

2. Composition

Each ml contains:

Active substance:
Butorphanol 10.0 mg
(Equivalent to 14.58 mg butorphanol tartrate)

Excipient:
Benzethonium chloride 0.10 mg

Clear, colourless solution.

3. Target species

Dogs, cats and horses.

4. Indications for use

Dog
As an analgesic:
- For relief of mild to moderate visceral pain.

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

As a premedicant prior to general anaesthesia:
- For use in combination with acepromazine to provide analgesia and sedation prior to induction of general anaesthesia. A dose-related reduction in the dose of induction-anaesthetic agent (propofol or thiopentone) is also provided.
- For premedication, give as the sole pre-anaesthetic agent.

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.

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).

5. Contraindications

All target species:

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

Horse:

Butorphanol/detomidine hydrochloride combination:

Do not use in horses with a pre-existing cardiac dysrhythmia or bradycardia.
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 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 (see section Other information). 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 is used as a sole agent in cats.
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 of the dose will not increase intensity or duration of desired effects.

Special precautions for safe use in the target species:

For 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 veterinary medicinal 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 on 'interaction with other medicinal products and other forms of interaction').
The safety of the veterinary medicinal product in puppies, kitten and foals has not been established and therefore in these animals the veterinary medicinal product should only be used according to a benefit-risk assessment by the responsible veterinary surgeon.

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

Cat:
Use of either insulin syringes or 1 ml graduated syringes is recommended.

Horse:
The use of the veterinary medicinal 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Butorphanol has opioid 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. In case of accidental self-injection, 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 any splashes from skin and eyes immediately.

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.
See also the section on 'Contraindications'.

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 on 'Dosage for each species, routes and method of administration' and subsection 'Special precautions for safe use in the target species').

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.

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.

Major incompatibilities:
Butorphanol must not be mixed with other veterinary medicinal products in the same syringe with the exception of the following combinations: butorphanol/medetomidine, butorphanol/medetomidine/ ketamine and butorphanol/acepromazine.

7. Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Sedation[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[b] Ataxia[c], Increased motor activity[d], Shivering Restlessness, Excitatory locomotor effects (e.g. pacing)[e] Digestive tract hypomotility[f]
Undetermined frequency (cannot be estimated from the available data):	Cardiac depression[g] Respiratory depression[g]

[a] Mild sedation may occur in approximately 15% of horses following administration of butorphanol as a sole agent.

[b] On intramuscular injection.

[c] Mild ataxia may persist for 3 to 10 minutes but ataxia can also last for 1 – 2 hours in some cases. Mild to severe ataxia may be encountered in combination with

detomidine, but horses are unlikely to collapse. Normal precautions should be observed to prevent injury (see section Special warnings).

[d] Can last for 1-2 hours in some cases.

[e] After a bolus i.v. injection at the maximum label dose (0.1 mg/kg body weight) in clinically normal horses.

[f] In normal horses, although there is no decrease in gastrointestinal transit time. These effects are dose-related, and generally minor and transient.

[g] When used in combination with alpha2-adrenoceptor agonists, cardiopulmonary system depression may be fatal in rare cases.

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Ataxia[a] Anorexia[a] Diarrhoea[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Sedation Respiratory depression[b] (e.g. decreased respiratory rate) Cardiac depression[b] (e.g. bradycardia[c], low blood pressure[d])
Undetermined frequency (cannot be estimated from the available data):	Injection site pain[e] Digestive tract hypomotility

[a] Transient.

[b] The degree of depression is dose-dependent. If respiratory depression occurs, naloxone may be used as an antidote. Moderate to marked cardiopulmonary depression may occur if butorphanol is given rapidly by intravenous injection.

[c] When using butorphanol as a pre-anaesthetic, the use of an anticholinergic such as atropine, will protect the heart against possible narcotic-induced bradycardia.

[d] A decrease in diastolic pressure (see section Special warnings).

[e] On intramuscular injection.

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory depression[a] Mydriasis Excitation
Undetermined frequency (cannot be estimated from the available data):	Injection site pain[b] Sedation, Disorientation Anxiety Dysphoria

[a] Naloxone may be used as an antidote.

[b] On 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

Dog and cat: Intravenous, intramuscular and subcutaneous use.
Horse: Intravenous use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 anesthesia 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 hydrochloride
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 ‘special warnings – Major incompatibilities’).		

*Depending on degree of sedation required**:** 0.01 mg/kg: For sedation and as a premedicant to barbiturate anaesthesia

**Depending on degree of sedation required 0.025 mg/kg: For profound sedation and as a premedicant to ketamine anaesthesia

For use as a premedicant/pre-anaesthetic:
- When the veterinary medicinal 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 veterinary medicinal 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 'special warnings – Major incompatibilities').	

* 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 'special warnings – Major incompatibilities').			

* 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 ‘special warnings – Major incompatibilities’).		

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 'special warnings – Major incompatibilities').			

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.		

Before this veterinary medicinal product is combined and administered in the same syringe as another veterinary medicinal product always refer to the section on 'Special warnings – Major incompatibilities'.
The maximum number of vial punctures when using needle sizes 21G and 23G should not exceed 100 and when using a 18G needle, the maximum should not exceed 40.

9. Advice on correct administration

Not applicable.

10. Withdrawal periods

Meat and offal: zero days.
Not authorised for use in mares producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41821/4037

Pack sizes: Cardboard box containing a glass vial of 10 or 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:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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 15-60 minutes.

POM-V

Gavin Hall
Approved: 08 May 2025