

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butomidor 10 mg/ml solution for injection for horses, dogs and cats (AT, BE, DE, EL, ES, LT, LV, NL, PT, SI)

Torpudor vet 10 mg/ml solution for injection for horses, dogs and cats (FI)

Butomidor vet. 10 mg/ml solution for injection for horses, dogs and cats (DK, IS, SE, NO)

Butador 10 mg/ml solution for injection for horses, dogs and cats (FR, IE, UK(NI))

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Butorphanol 10 mg  
(as butorphanol tartrate 14.58 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
Sodium chloride	
Water for injections	

Clear, colourless to almost colourless solution for injection.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Horses, dogs, cats

### 3.2 Indications for use for each target species

#### Horses

##### **As an analgesic**

For the short term relief of pain such as colic of gastrointestinal tract origin.

##### **As a sedative and pre-anaesthetic**

In combination with  $\alpha_2$ -adrenoceptor agonists (detomidine, romifidine, xylazine):

For therapeutic and diagnostic procedures such as minor standing surgery and sedation of intractable patients.

#### Dogs, cats

##### **As an analgesic**

For relief of moderate visceral pain e.g. pre- and post-surgical as well as post-traumatic pain.

##### **As a sedative**

In combination with  $\alpha_2$ -adrenoceptor agonists (medetomidine).

### **As a pre-anaesthetic**

Part of anaesthetic regime (medetomidine, ketamine).

### **3.3 Contraindications**

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use for treatment of animals with severe dysfunction of the liver and kidneys, in case of cerebral injury or organic brain lesions and in animals with obstructive respiratory diseases, heart dysfunctions or spastic conditions.

For combination use with  $\alpha_2$ -agonists in horses:

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 combination during pregnancy.

### **3.4 Special warnings**

The precautionary measures required for contact with animals should be followed and stress factors for the animals should be avoided.

In cats, individual response to butorphanol may be variable. In the absence of an adequate analgesic response, an alternative analgesic agent should be used.

Increasing of 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:

The safety of the veterinary medicinal product in puppies, kitten and foals has not been established. Use of the veterinary medicinal product in these groups should be on the basis of a risk-benefit analysis 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, butorphanol should only be used after a risk-benefit evaluation by the responsible veterinarian. If respiratory depression occurs, naloxone may be used as an antidote.

Sedation may be noted in treated animals. The combination of butorphanol and  $\alpha_2$ -adrenoceptor agonists should be used with caution in animals with cardiovascular disease. The concurrent use of anticholinergic drugs, e.g. atropine should be considered. Routine cardiac auscultation should be performed prior to use in combination with  $\alpha_2$ -adrenoceptor agonists.

Administration of butorphanol and romifidine in one syringe should be avoided due to increased bradycardia, heart block and ataxia.

#### Horses

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 when treating horses, the location for the treatment should be chosen carefully.

#### Dogs

In dogs with MDR1 mutation reduce dose by 25 - 50 %.

#### Cats

Cats should be weighed to ensure that the correct dose is calculated. An appropriate graduated syringe must be used to allow accurate administration of the required dose volume (e.g. insulin syringe or 1 ml graduated syringe). If repeated administrations are required, use different injection sites.

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

Butorphanol has opioid-like activity. Precautions should be taken to avoid accidental injection/self-injection with this potent drug. The most frequent adverse effects of butorphanol in humans are drowsiness, sweating, nausea, dizziness and vertigo and may occur following unintended 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 splashes from skin and eyes immediately.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

**Horses:**

Very common (>1 animal / 10 animals treated):	Ataxia <sup>1</sup> , Sedation <sup>2</sup> .
Undetermined frequency (cannot be estimated from the available data):	Involuntary movement <sup>3</sup> ; Digestive tract hypomotility <sup>4</sup> ; Respiratory depression <sup>5</sup> ; Cardiac depression.

<sup>1</sup> Lasting about 3 to 15 minutes.

<sup>2</sup> Mild.

<sup>3</sup> Running movements.

<sup>4</sup> Mild and transient. Any reduction of gastrointestinal motility caused by butorphanol may be enhanced by the concomitant use of  $\alpha_2$ -agonists.

<sup>5</sup> The respiratory depressive effects of  $\alpha_2$ -agonists may be enhanced by concomitant butorphanol, particularly if respiratory function is already impaired.

**Dogs:**

Rare (1 to 10 animals / 10,000 animals treated):	Ataxia; Anorexia; Diarrhoea.
Undetermined frequency (cannot be estimated from the available data):	Respiratory depression; Cardiac depression; Injection site pain <sup>1</sup> ; Digestive tract hypomotility.

<sup>1</sup> Associated with intramuscular administration.

**Cats:**

Rare	Ataxia;
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(1 to 10 animals / 10,000 animals treated):	Anorexia; Diarrhoea.
Undetermined frequency (cannot be estimated from the available data):	Respiratory depression; Cardiac depression; Injection site pain <sup>1</sup> ; Digestive tract hypomotility; Excitation, Anxiety; Sedation, Mydriasis, Disorientation; Dysphoria.

<sup>1</sup> Associated with intramuscular administration.

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:

Butorphanol crosses the placental barrier and penetrates into milk. Studies in laboratory species have not produced any evidence of teratogenic effects.

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

### 3.8 Interaction with other medicinal products and other forms of interaction

The concomitant administration of other drugs which are metabolised in the liver may enhance the effect of butorphanol.

Butorphanol used with concurrently administered anaesthetics, centrally sedative or respiratory depressive drugs produces additive effects. Any use of butorphanol in this context requires acute control and a careful adaptation of the dose.

Administration of butorphanol may remove the analgesic effect in animals, which have already received pure  $\mu$ -opioid analgesics.

### 3.9 Administration routes and dosage

For intravenous (i.v.), intramuscular (i.m.) or subcutaneous (s.c.) use.

Horses: Intravenous

Dogs: Intravenous, subcutaneous or intramuscular

Cats: Intravenous or subcutaneous

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

#### Horses

##### **As an analgesic**

##### Monotherapy:

0.1 mg/kg (1 ml/100 kg bw) i.v.

##### **As a sedative and as a pre-anaesthetic**

##### With detomidine:

Detomidine: 0.012 mg/kg i.v., followed within 5 minutes by  
Butorphanol: 0.025 mg/kg (0.25 ml /100 kg bw) i.v.

**With romifidine:**

Romifidine: 0.05 mg/kg i.v., followed within 5 minutes by  
Butorphanol: 0.02 mg/kg (0.2 ml /100 kg bw) i.v..

**With xylazine:**

Xylazine: 0.5 mg/kg i.v., followed after 3 - 5 minutes by  
Butorphanol: 0.05 – 0.1 mg/kg (0.5 - 1 ml /100 kg bw) i.v..

**Dogs**

**As an analgesic**

**Monotherapy:**

0.1 - 0.4 mg/kg (0.01 – 0.04 ml/kg bw) slowly i.v. (in the lower to medium dose range) as well as i.m., s.c..

For post-operative pain control the injection should be administered 15 minutes before the end of anaesthesia in order to achieve sufficient pain relief during the recovery phase.

**As a sedative**

**With medetomidine:**

Butorphanol: 0.1 mg/kg (0.01 ml/kg bw) i.v., i.m.

Medetomidine: 0.01 mg/kg i.v., i.m.

**As a pre-anaesthetic**

**With medetomidine and ketamine:**

Butorphanol: 0.1 mg/kg (0.01 ml/kg bw) i.m.

Medetomidine: 0.025 mg/kg i.m., followed after 15 minutes by

Ketamine: 5 mg/kg i.m.

It is only possible to use atipamezole 0.1 mg/kg body weight for medetomidine-antagonisation when ketamine action has ceased.

**Cats**

**As an analgesic**

**Monotherapy:**

15 minutes prior to recovery

either: 0.4 mg/kg (0.04 ml/kg bw) s.c.

or: 0.1 mg/kg (0.01 ml/kg bw) i.v.

**As a sedative**

**With medetomidine:**

Butorphanol: 0.4 mg/kg (0.04 ml/kg bw) s.c.

Medetomidine: 0.05 mg/kg s.c.

For wound debridement an additional local anaesthesia is recommended.

Medetomidine-antagonisation is possible with atipamezole 0.125 mg/kg body weight.

**As a pre-anaesthetic**

**With medetomidine and ketamine:**

Butorphanol: 0.1 mg/kg (0.01 ml/kg bw) i.v.

Medetomidine: 0.04 mg/kg i.v.

Ketamine: 1.5 mg/kg i.v.

It is only possible to use atipamezole 0.1 mg/kg body weight for medetomidine-antagonisation when ketamine action has ceased.

Butorphanol is intended for use where short (horses and dogs) and short to medium (cats) analgesia is required. The dose may be repeated as required. The need for and timing of repeated treatment will be based on clinical response. For information on the duration of analgesia see section 4.2.

Rapid intravenous injection should be avoided.

The stopper must not be punctured more than 25 times.

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

#### Horses

Increased dosages could result in respiratory depression as a general opioid effect. Intravenous doses of 1.0 mg/kg (10 x the recommended dose), repeated at 4-hourly intervals for 2 days, led to transient adverse effects, including pyrexia, tachypnoea, CNS signs (hyperexcitability, restlessness, mild ataxia leading to somnolence) and gastrointestinal hypomotility, sometimes with abdominal discomfort. An opioid antagonist (e.g. Naloxone) may be used as an antidote.

#### Dogs, cats

Miosis (dog)/Mydriasis (cat), respiratory depression, hypotension, disorders of the cardiovascular system and in severe cases respiratory inhibition, shock and coma. Depending on the clinical situation counter-measures should be taken under intense medical monitoring. Monitoring is required for a minimum of 24 hours.

### **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**

*(to be completed in accordance with national requirements)*

### **3.12 Withdrawal periods**

#### Horses

Meat and offal: zero days

Milk: zero hours

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QN02AF01**

### **4.2 Pharmacodynamics**

Butorphanol is a centrally acting analgesic from the group of synthetic opioids with an agonistic-antagonistic effect, 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.

Analgesia generally occurs within 15 minutes following administration in horse, dog and cat. After a single intravenous dose in the horse analgesia usually lasts up to 2 hours. In the dog it lasts up to 30 minutes after a single intravenous administration. In cats with visceral pain analgesic effects have been

demonstrated for up to 6 hours. In cats with somatic pain duration of analgesia has been considerably shorter.

Increased doses do not correlate with increased analgesia, a dosage of about 0.4 mg/kg leads to a ceiling effect.

Butorphanol has minimal cardiopulmonary depressant activity in the target species. It does not cause histamine release in horses. In combination with  $\alpha_2$ -agonists it causes additive and synergistic sedation.

#### **4.3 Pharmacokinetics**

Post parenteral administration absorption of the veterinary medicinal product is rapid and almost complete with serum peak levels occurring after 0.5 - 1.5 hours. It is highly bound to plasma proteins (up to 80 %). Metabolism is rapid and mainly occurs in the liver. Two inactive metabolites are produced. The elimination occurs mainly through urine (to a major extent) and faeces.

Horses: Volume of distribution is large after i.v. administration (2.1 l/kg) suggesting wide distribution into tissues. Terminal half life is short: about 44 minutes. 97 % of the dose after i.v. administration in the horse will be eliminated in less than 5 hours.

Dogs: Volume of distribution is large after i.v. administration (4.4 l/kg) suggesting wide distribution into tissues. Terminal half life is short: about 1.7 hours.

Cats: Volume of distribution is large after i.v. administration (7.4 l/kg) suggesting wide distribution into tissues. Terminal half life is short: about 4.1 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**

This veterinary medicinal product does not require any special temperature storage conditions. Keep the vial in the outer carton in order to protect from light.

#### **5.4 Nature and composition of immediate packaging**

Clear glass type I vials with bromobutyl rubber stoppers and aluminium caps.

Package sizes: 1 x 10 ml, 5 x 10 ml, 10 x 10 ml, 1 x 50 ml.

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**

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

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

**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>).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box (10 ml, 5 x 10 ml, 10 x 10 ml and 50 ml)

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Butomidor 10 mg/ml solution for injection (AT, BE, DE, EL, ES, LT, LV, NL, PT, SI)  
Torpudor vet 10 mg/ml solution for injection (FI)  
Butomidor vet. 10 mg/ml solution for injection (DK, IS, SE, NO)  
Butador 10 mg/ml solution for injection (FR, IE, UK(NI))

Butorphanol

**2. STATEMENT OF ACTIVE SUBSTANCES**

Butorphanol 10 mg/ml

**3. PACKAGE SIZE**

10 ml  
5 x 10 ml  
10 x 10 ml  
50 ml

**4. TARGET SPECIES**

Horses, dogs, cats

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Horses: i.v.

Dogs: i.v., s.c., i.m.

Cats: i.v., s.c.

**7. WITHDRAWAL PERIODS****Withdrawal period:**

Horses:

Meat and offal: zero days

Milk: zero hours

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days.

**9. SPECIAL STORAGE PRECAUTIONS**

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

**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**

VetViva Richter (logo)

**14. MARKETING AUTHORISATION NUMBERS****15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

10 ml and 50 ml clear glass vial type I with bromobutyl rubber stopper and alu-caps

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Butomidor (AT, BE, DE, EL, ES, LT, LV, NL, PT, SI)

Torpudor vet (FI)

Butomidor vet. (DK, IS, SE, NO)

Butador (FR, IE, UK(NI))



Horses, dogs, 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 by .....

10 ml  
50 ml

VetViva Richter (logo)

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Butomidor 10 mg/ml solution for injection for horses, dogs and cats (AT, BE, DE, EL, ES, LT, LV, NL, PT, SI)

Torpudor vet 10 mg/ml solution for injection for horses, dogs and cats (FI)

Butomidor vet. 10 mg/ml solution for injection for horses, dogs and cats (DK, IS, SE, NO)

Butador 10 mg/ml solution for injection for horses, dogs and cats (FR, IE, UK(NI))

### 2. Composition

Each ml contains:

#### Active substance:

Butorphanol 10 mg  
(as butorphanol tartrate 14.58 mg)

#### Excipient:

Benzethonium chloride 0.1 mg

Clear, colourless to almost colourless solution for injection.

### 3. Target species

Horses, dogs, cats

### 4. Indications for use

#### Horses

##### **As an analgesic**

For the short term relief of pain such as colic of gastrointestinal tract origin.

##### **As a sedative and pre-anaesthetic**

In combination with  $\alpha_2$ -adrenoceptor agonists (detomidine, romifidine, xylazine):

For therapeutic and diagnostic procedures such as minor standing surgery and sedation of intractable patients.

#### Dogs, cats

##### **As an analgesic**

For relief of moderate visceral pain e.g. pre- and post-surgical as well as post-traumatic pain.

##### **As a sedative**

In combination with  $\alpha_2$ -adrenoceptor agonists (medetomidine).

##### **As a pre-anaesthetic**

Part of anaesthetic regime (medetomidine, ketamine).

### 5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.  
Do not use for treatment of animals with severe dysfunction of the liver and kidneys, in case of cerebral injury or organic brain lesions and in animals with obstructive respiratory diseases, heart dysfunctions or spastic conditions.

For combination use with  $\alpha_2$ -agonists in horses:

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 combination during pregnancy.

## **6. Special warnings**

### Special warnings:

The precautionary measures required for contact with animals should be followed and stress factors for the animals should be avoided.

In cats, individual response to butorphanol may be variable. In the absence of an adequate analgesic response, an alternative analgesic agent should be used.

Increasing of the dose may not increase the intensity or duration of analgesia.

### Special precautions for safe use in the target species:

The safety of the veterinary medicinal product in puppies, kitten and foals has not been established. Use of the veterinary medicinal product in these groups should be on the basis of a risk-benefit analysis 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, butorphanol should only be used after a risk-benefit evaluation by the responsible veterinarian. If respiratory depression occurs, naloxone may be used as an antidote.

Sedation may be noted in treated animals. The combination of butorphanol and  $\alpha_2$ -adrenoceptor agonists should be used with caution in animals with cardiovascular disease. The concurrent use of anticholinergic drugs, e.g. atropine should be considered. Routine cardiac auscultation should be performed prior to use in combination with  $\alpha_2$ -adrenoceptor agonists.

Administration of butorphanol and romifidine in one syringe should be avoided due to increased bradycardia, heart block and ataxia.

### Horses

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 when treating horses, the location for the treatment should be chosen carefully.

### Dogs

In dogs with MDR1 mutation reduce dose by 25 - 50 %.

### Cats

Cats should be weighed to ensure that the correct dose is calculated. An appropriate graduated syringe must be used to allow accurate administration of the required dose volume (e.g. insulin syringe or 1 ml graduated syringe). If repeated administrations are required, use different injection sites.

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

Butorphanol has opioid-like activity. Precautions should be taken to avoid accidental injection/self-injection with this potent drug. The most frequent adverse effects of butorphanol in humans are drowsiness, sweating, nausea, dizziness and vertigo and may occur following unintended 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 splashes from skin and eyes immediately.

Pregnancy and lactation:

Butorphanol crosses the placental barrier and penetrates into milk. Studies in laboratory species have not produced any evidence of teratogenic effects.

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

Interaction with other medicinal products and other forms of interaction:

The concomitant administration of other drugs which are metabolised in the liver may enhance the effect of butorphanol.

Butorphanol used with concurrently administered anaesthetics, centrally sedative or respiratory depressive drugs produces additive effects. Any use of butorphanol in this context requires acute control and a careful adaptation of the dose.

Administration of butorphanol may remove the analgesic effect in animals, which have already received pure  $\mu$ -opioid analgesics.

Overdose:

Horses

Increased dosages could result in respiratory depression as a general opioid effect. Intravenous doses of 1.0 mg/kg (10 x the recommended dose), repeated at 4-hourly intervals for 2 days, led to transient adverse effects, including pyrexia, tachypnoea, CNS signs (hyperexcitability, restlessness, mild ataxia leading to somnolence) and gastrointestinal hypomotility, sometimes with abdominal discomfort. An opioid antagonist (e.g. Naloxone) may be used as an antidote.

Dogs, cats

Miosis (dog)/Mydriasis (cat), respiratory depression, hypotension, disorders of the cardiovascular system and in severe cases respiratory inhibition, shock and coma. Depending on the clinical situation counter-measures should be taken under intense medical monitoring. Monitoring is required for a minimum of 24 hours.

**<Special restrictions for use and special conditions for use:>**  
*(to be completed in accordance with national requirements)*

Major incompatibilities:

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

## 7. Adverse events

**Horses:**

Very common (>1 animal / 10 animals treated):

Ataxia (incoordination)<sup>1</sup>, sedation<sup>2</sup>.

Undetermined frequency (cannot be estimated from the available data):

Involuntary movement<sup>3</sup>, digestive tract hypomotility (slow movement)<sup>4</sup>, respiratory depression<sup>5</sup>, cardiac depression.

<sup>1</sup> Lasting about 3 to 15 minutes.

<sup>2</sup> Mild.

<sup>3</sup> Running movements.

<sup>4</sup> Mild and transient. Any reduction of gastrointestinal motility caused by butorphanol may be enhanced by the concomitant use of  $\alpha_2$ -agonists.

<sup>5</sup> The respiratory depressive effects of  $\alpha_2$ -agonists may be enhanced by concomitant butorphanol, particularly if respiratory function is already impaired.

#### **Dogs:**

Rare (1 to 10 animals / 10,000 animals treated):

Ataxia (incoordination), anorexia (loss of appetite), diarrhoea.

Undetermined frequency (cannot be estimated from the available data):

Respiratory depression, cardiac depression, injection site pain<sup>1</sup>, digestive tract hypomotility (slow movement).

<sup>1</sup> Associated with intramuscular administration.

#### **Cats:**

Rare (1 to 10 animals / 10,000 animals treated):

Ataxia (incoordination), anorexia (loss of appetite), diarrhoea.

Undetermined frequency (cannot be estimated from the available data):

Respiratory depression, cardiac depression, injection site pain<sup>1</sup>, digestive tract hypomotility (slow movement), excitation, anxiety, sedation, mydriasis, disorientation, dysphoria.

<sup>1</sup> Associated with intramuscular administration.

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.

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

For intravenous (i.v.), intramuscular (i.m.) or subcutaneous (s.c.) use.

Horses: Intravenous

Dogs: Intravenous, subcutaneous or intramuscular

Cats: Intravenous or subcutaneous

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

### Horses

#### **As an analgesic**

##### Monotherapy:

0.1 mg/kg (1 ml/100 kg bw) i.v.

#### **As a sedative and as a pre-anaesthetic**

##### With detomidine:

Detomidine: 0.012 mg/kg i.v., followed within 5 minutes by

Butorphanol: 0.025 mg/kg (0.25 ml /100 kg bw) i.v.

##### With romifidine:

Romifidine: 0.05 mg/kg i.v., followed within 5 minutes by  
Butorphanol: 0.02 mg/kg (0.2 ml /100 kg bw) i.v.

With xylazine:

Xylazine: 0.5 mg/kg i.v., followed after 3 - 5 minutes by  
Butorphanol: 0.05 – 0.1 mg/kg (0.5 - 1 ml /100 kg bw) i.v.

Dogs

**As an analgesic**

Monotherapy:

0.1 - 0.4 mg/kg (0.01 – 0.04 ml/kg bw) slowly i.v. (in the lower to medium dose range) as well as i.m., s.c..

For post-operative pain control the injection should be administered 15 minutes before the end of anaesthesia in order to achieve sufficient pain relief during the recovery phase.

**As a sedative**

With medetomidine:

Butorphanol: 0.1 mg/kg (0.01 ml/kg bw) i.v., i.m.

Medetomidine: 0.01 mg/kg i.v., i.m.

**As a pre-anaesthetic**

With medetomidine and ketamine:

Butorphanol: 0.1 mg/kg (0.01 ml/kg bw) i.m.

Medetomidine: 0.025 mg/kg i.m., followed after 15 minutes by

Ketamine: 5 mg/kg i.m.

It is only possible to use atipamezole 0.1 mg/kg body weight for medetomidine-antagonisation when ketamine action has ceased.

Cats

**As an analgesic**

Monotherapy:

15 minutes prior to recovery

either: 0.4 mg/kg (0.04 ml/kg bw) s.c.

or: 0.1 mg/kg (0.01 ml/kg bw) i.v.

**As a sedative**

With medetomidine:

Butorphanol: 0.4 mg/kg (0.04 ml/kg bw) s.c.

Medetomidine: 0.05 mg/kg s.c.

For wound debridement an additional local anaesthesia is recommended.

Medetomidine-antagonisation is possible with atipamezole 0.125 mg/kg body weight.

**As a pre-anaesthetic**

With medetomidine and ketamine:

Butorphanol: 0.1 mg/kg (0.01 ml/kg bw) i.v.

Medetomidine: 0.04 mg/kg i.v.

Ketamine: 1.5 mg/kg i.v.

It is only possible to use atipamezole 0.1 mg/kg body weight for medetomidine-antagonisation when ketamine action has ceased.

The stopper must not be punctured more than 25 times.

## **9. Advice on correct administration**

Butorphanol is intended for use where short (horses and dogs) and short to medium (cats) analgesia is required. The dose may be repeated as required. The need for and timing of repeated treatment will be based on clinical response. Analgesia generally occurs within 15 minutes following administration in horse, dog and cat. After a single intravenous dose in the horse analgesia usually lasts up to 2 hours. In the dog it lasts up to 30 minutes after a single intravenous administration. In cats with visceral pain analgesic effects have been demonstrated for up to 6 hours. In cats with somatic pain duration of analgesia has been considerably shorter.

Rapid intravenous injection should be avoided.

Do not mix the veterinary medicinal product with other veterinary medicinal products in one syringe.

## **10. Withdrawal periods**

### Horses

Meat and offal: zero days

Milk: zero hours

## **11. Special storage precautions**

Keep out of the sight and reach of children.

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

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton 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 therefrom 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**

XXXXX

### Package sizes:

1 x 10 ml, 5 x 10 ml, 10 x 10 ml, 1 x 50 ml.

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

{MM/YYYY}

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>).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

<Local representatives <and contact details to report suspected adverse reactions>:

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

## **<17. Other information>**

