# PARTICULARS TO APPEAR ON THE OUTER PACKAGE
**(10 ml, 5 x 10 ml, 10 x 10 ml and 50 ml)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butador 10 mg/ml solution for injection

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 GmbH

## 14. MARKETING AUTHORISATION NUMBERS

GB: Vm 57446/5006
NI: Vm 57446/3006

## 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

Butador

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 …….

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 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 μ-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.

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)[1], sedation[2].

Undetermined frequency (cannot be estimated from the available data):
Involuntary movement[3], digestive tract hypomotility (slow movement)[4], respiratory depression[5], cardiac depression.

[1] Lasting about 3 to 15 minutes.
[2] Mild.
[3] Running movements.
[4] Mild and transient. Any reduction of gastrointestinal motility caused by butorphanol may be enhanced by the concomitant use of $\alpha_2$-agonists.
[5] 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[1], digestive tract hypomotility (slow movement).

[1] 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[1], digestive tract hypomotility (slow movement), excitation, anxiety, sedation, mydriasis, disorientation, dysphoria.

[1] 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 at https://www.gov.uk/report-veterinary-medicine-problem.

## 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.
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

GB: Vm 57446/5006
NI: Vm 57446/3006

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

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
Tel: +43 (0)664 8455326
E-mail: adverse.events@vetviva.com

## 17. Other information

POM-V

Gavin Hall

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