

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD CARTON**

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

Buprecare Multidose 0.3 mg/ml Solution for Injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Buprenorphine (as buprenorphine hydrochloride) 0.3 mg/ml.

**3. PACKAGE SIZE**

10 ml

**4. TARGET SPECIES**

Dogs and cats.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

For intramuscular or intravenous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp: {mm/yyyy}  
Once broached, use within 28 days

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.  
Keep the vial in the outer carton in order to protect from light.  
Do not refrigerate or freeze.

**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**

Company logo

**14. MARKETING AUTHORISATION NUMBER**

Vm 32742/4025

**15. BATCH NUMBER**

Lot {number}

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

**10 ml bottle**

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

Buprecare Multidose

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

Buprenorphine (as buprenorphine hydrochloride) 0.3 mg/ml.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use within 28 days

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats

### 2. Composition

Each ml contains:

**Active substance:**

Buprenorphine 0.3 mg (as buprenorphine hydrochloride).

**Excipient:**

Chlorocresol 1.35 mg

Clear, colourless solution.

### 3. Target species

Dogs and cats.

### 4. Indications for use

DOGS:

Post-operative analgesia.

Potentialiation of the sedative effects of centrally- acting agents.

CATS:

Post-operative analgesia.

### 5. Contraindications

Do not administer by the intrathecal or peridural route.

Do not use pre-operatively for caesarean section. Please refer to section "Special warnings, pregnancy and lactation".

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

### 6. Special warnings

Special precautions for safe use in the target species:

Use of the veterinary medicinal product in the below circumstances should only be in accordance with the benefit/risk assessment by the responsible veterinarian.

Buprenorphine may occasionally cause significant respiratory depression and, as with other opioid drugs, care should be taken when treating animals with impaired respiratory function or animals that are receiving drugs that can cause respiratory depression.

Buprenorphine should be used with caution in animals with impaired liver function, especially biliary tract disease, as the substance is metabolised by the liver and its intensity and duration of action may be affected in some animals.

In cases of renal, cardiac or hepatic dysfunction, or shock, there may be greater risk associated with the use of the product. Safety has not been fully evaluated in clinically compromised cats.

The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age.

Repeated administration earlier than the recommended repeat interval suggested in Section "Dosage for each species, routes and method of administration" is not recommended.

Long-term safety of buprenorphine in cats has not been investigated beyond 5 consecutive days of administration.

The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.

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

Wash hands/affected area thoroughly after any accidental spillage.

As buprenorphine has opioid-like activity, care should be taken to avoid accidental self-injection.

In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Following eye contamination or skin contact, wash thoroughly with cold running water, seek medical advice if irritation persists.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of a teratogenic effect. However, these studies have shown post-implantation losses and early foetal deaths. Although post-implantation losses and early peri-natal deaths were observed, these may have resulted from a reduction in parental body condition during gestation and in post-natal care owing to sedation of the mothers. As reproductive toxicity studies have not been conducted in the target species, use only according to the benefit-risk assessment by the responsible veterinarian.

The product should not be used pre-operatively in cases of caesarean section, due to the risk of respiratory depression in the offspring periparturiently and should only be used post-operatively with special care (see section on lactation below).

Studies in lactating rats have shown that, after intramuscular administration of buprenorphine, concentrations of unchanged buprenorphine in the milk equalled or exceeded that in the plasma. It is likely that buprenorphine will be excreted in the milk of other species:

Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Buprenorphine may cause some drowsiness, which may be potentiated by other centrally-acting agents, including tranquilisers, sedatives and hypnotics.

There is evidence in humans to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist, and that when buprenorphine is employed within the normal therapeutic range, standard doses of opioid agonist may be administered before the effects of the former have ended without compromising analgesia. However, it is recommended that buprenorphine is not used in conjunction with morphine or other opioid-type analgesics, e.g. etorphine, fentanyl, pethidine, methadone, papaveretum or butorphanol.

Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone and xylazine. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

Overdose:

In case of overdosage, supportive measures should be instituted and if appropriate, naloxone or respiratory stimulants may be used.

When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.

In toxicological studies of buprenorphine hydrochloride in dogs, biliary hyperplasia was observed after oral administration for one year at dose levels of 3.5 mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5 mg/kg/day for 3 months. This is well in excess of any clinical dose regimen in the dog.

Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as doxapram are also effective in man. Because of the prolonged duration of effect of buprenorphine in comparison to such drugs, they may need to be administered repeatedly or by continuous infusion. Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine. Please refer to "Special precautions for safe use in the target species" and to section "Adverse events".

Major incompatibilities:

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

Special restrictions for use and special conditions for use:

## 7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypertension (high blood pressure) Tachycardia (rapid heart rate) Sedation <sup>1</sup>
Undetermined frequency (cannot be estimated from the available data):	Hypersalivation Bradycardia (slow heart rate) Hypothermia (low body temperature) Agitation Dehydration Miosis (constricted pupils) Respiratory depression <sup>2</sup>

<sup>1</sup> May occur when used to provide analgesia at dose levels higher than those recommended.

<sup>2</sup> Significant, see section “special warnings”.

Cats:

Common (1 to 10 animals / 100 animals treated):	Mydriasis (dilated pupils) Euphoria (excessive purring, pacing, rubbing) <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):	Sedation <sup>2</sup>
Undetermined frequency (cannot be estimated from the available data):	Respiratory depression <sup>3</sup>

<sup>1</sup> Usually resolve within 24 hours.

<sup>2</sup> May occur when used to provide analgesia at dose levels higher than those recommended.

<sup>3</sup> Significant, see section “special warnings”.

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: {national system details}

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

For intramuscular or intravenous use.

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

Species	Post-Operative Analgesia	Potential of Sedation
Dogs	10–20 µg per kg (0.3–0.6 ml per 10 kg) For further pain relief, repeat if necessary after 3–4 hours with 10 µg per kg or 5–6 hours with 20 µg per kg.	10–20 µg per kg (0.3–0.6 ml per 10 kg).
Cats	10–20 µg per kg (0.3–0.6 ml per 10 kg), repeated if necessary, once, after 1-2 hours.	-

While sedative effects are present by 15 minutes after administration, analgesic activity becomes apparent after approximately 30 minutes. To ensure that analgesia is present during surgery and immediately on recovery, the product should be administered pre-operatively as part of premedication.

When administered for potentiation of sedation or as part of premedication, the dose of other centrally-acting agents, such as acepromazine or medetomidine, should be reduced. The reduction will depend on the degree of sedation required, the individual animal, the type of other agents included in premedication and how anaesthesia is to be induced and maintained. It may also be possible to reduce the amount of inhalational anaesthetic used.

Animals administered opioids possessing sedative and analgesic properties may show variable responses. Therefore, the responses of individual animals should be monitored and subsequent doses should be adjusted accordingly. In some cases repeat doses may fail to provide additional analgesia. In these cases, consideration should be given to using a suitable injectable NSAID.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

The vial seal may be punctured up to a maximum of 30 times.

## 9. Advice on correct administration

## 10. Withdrawal period

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25°C.

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

Do not refrigerate or freeze.

Shelf life after first opening the immediate packaging: 28 days.

Do not use this veterinary medicinal product after the expiry date stated on the label and the carton after “Exp”.

The expiry date refers to the last day of that month.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

## **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.

Any unused product must be disposed of in accordance with the Misuse of Drugs Regulations 2001 (UK)

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Vm 32742/4025

Pack size:

1 vial with 10ml solution for injection.

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](http://www.gov.uk).

## **16. Contact details**

### Marketing authorisation holder:

Ecuphar NV  
Legeweg 157-i  
8020 Oostkamp  
Belgium

### Manufacturer responsible for batch release:

Produlab Pharma BV  
Forrellenweg 16  
NL 4941-SJ Raamsdonksveer  
The Netherlands

### Local representatives and contact details to report suspected adverse events:

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

Animalcare Ltd  
Moorside  
Monks Cross  
York, YO32 9LB  
United Kingdom  
Tel: +44 (0) 330 8189717  
E-mail: [animalcare@animalcare.co.uk](mailto:animalcare@animalcare.co.uk)

## **17. Other information**

Buprenorphine is a potent long-acting analgesic acting at opioid receptor sites in the central nervous system (CNS). Buprenorphine can potentiate the effects of other centrally-acting agents, but unlike most opiates, buprenorphine has, at clinical doses, only a limited sedative effect of its own. Buprenorphine exerts its analgesic effect via high-affinity binding to various subclasses of opiate receptors, particularly  $\mu$ , in the CNS.

At clinical dose levels for analgesia, buprenorphine binds to opiate receptors with high affinity and high receptor avidity, such that its dissociation from the receptor is slow, as demonstrated in *in vitro* studies. This property of buprenorphine could account for its longer duration of activity when compared to morphine. In circumstances where excessive opiate agonist is already bound to opiate receptors, buprenorphine can exert a narcotic antagonistic activity as a consequence of its high-affinity opiate receptor binding, such that an antagonistic effect on morphine equivalent to naloxone has been demonstrated.

Buprenorphine is rapidly absorbed after intra-muscular injection in various animal species and in man. Analgesic effects appear around 30 minutes after injection with peak effects usually being observed at about 1–1.5 hours.

Combined pharmacokinetic and pharmacodynamic studies in cats have demonstrated a marked delay between plasma concentrations and analgesic effect. Plasma concentrations of buprenorphine should not be used to formulate individual

animal dosage regimes, which should be determined by monitoring of the patient's response.

Buprenorphine has little effect on gastro-intestinal motility.

*Gavin Hall*  
Approved: 28 October 2025