ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1 vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic Multidose, 0.3mg/ml, Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 0.3 mg of Buprenorphine as Buprenorphine hydrochloride

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous or intramuscular use.
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}
Once broached, use within28 days by : _ ___/____/_____

9. SPECIAL STORAGE PRECAUTIONS

Keep vial in 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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER(S)

Vm 14966/3028

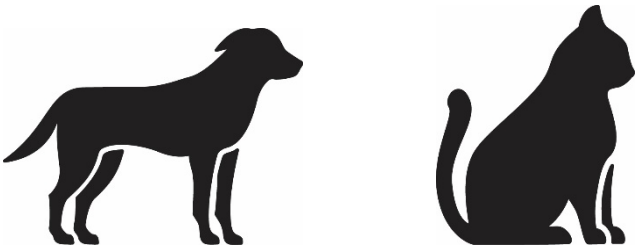
15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

0.3mg/ml of buprenorphine

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

Vetergesic Multidose, 0.3mg/ml, Solution for Injection for Dogs and Cats

2. Composition

Each ml contains:
Active substance:

Buprenorphine	0.3 mg
as buprenorphine hydrochloride	0.324 mg
Excipient(s):	
Chlorocresol	1.35 mg
as antimicrobial preservative	

Clear, colourless solution for injection.

3. Target species

Dogs and cats.

4. Indications for use

Dogs
Post-operative analgesia.
Potentiation 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.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
Buprenorphine may cause 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.
In case of renal, cardiac or hepatic dysfunction or shock, there may be greater risk associated with the use of the veterinary medicinal product. The benefit-risk assessment for using the veterinary medicinal product should be made by the attending veterinarian. Safety has not been fully evaluated in clinically compromised cats.
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 such animals.
The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age, therefore, use in such animals should be based on the benefit-risk assessment of the veterinarian.
Repeat administration earlier than the recommended repeat interval suggested in Section 3.9 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. The veterinary medicinal product should be used in accordance with the benefit-risk assessment of the attending veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
As buprenorphine has opioid-like activity, care should be taken to avoid self-injection. In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or label to the physician.
Following eye contamination or skin contact, wash thoroughly with cold running water. Seek medical advice if irritation persists.
Wash hands/affected area thoroughly after any accidental spillage.

Pregnancy:
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. 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 veterinary medicinal 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.

Lactation:
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. As it is likely that buprenorphine will be excreted in the milk of other species, use is not recommended during lactation. Use only according benefit: risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:
Buprenorphine may cause some drowsiness, which may be potentiated by other centrally acting agents, including tranquillisers, sedatives and hypnotics.
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, although 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.
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.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose:
When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.
In cases of overdosage, supportive measures should be instituted, and, if appropriate, naloxone or respiratory stimulants may be used.
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.
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.

Special restrictions for use and special conditions for use:
For administration only by a veterinarian or under their direct supervision.

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

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Hypertension (high blood pressure), Tachycardia (rapid heart rate) Sedation[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site pain, Local discomfort

Vocalisation[2]
Undetermined frequency (cannot be estimated from the available data):
Increased salivation Bradycardia (slow heart rate) Hypothermia (low body temperature), Dehydration Agitation Miosis (constricted pupils) Respiratory depression

[1] When used to provide analgesia
[2] Resulting from injection site pain or local discomfort

Cats:

Common (1 to 10 animals / 100 animals treated):
Mydriasis (dilated pupils) and signs of euphoria (excessive purring, pacing, rubbing)[1]
Rare (1 to 10 animals / 10,000 animals treated):
Sedation[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site pain, Local discomfort Vocalisation[3]
Undetermined frequency (cannot be estimated from the available data):
Respiratory depression

[1] Usually resolve within 24 hours.
[2] When used to provide analgesia
[3] Resulting from injection site pain or local discomfort

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 its local representative using the contact details shown below in this leaflet, or via your national reporting system
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

Shake well before use.
An appropriately graduated syringe must be used to allow accurate dosing.

Species	Route of Administration	Post-Operative Analgesia	Potentiation of Sedation
Dogs	Intramuscular or intravenous injection	10-20 µg per kg (0.3-0.6ml per 10kg). 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 (0.3-0.6ml per 10 kg).
Cats	Intramuscular or intravenous injection	10 – 20 µg per kg (0.3 – 0.6ml per 10kg), repeated if necessary, once, after 1-2 hours.	---

9. Advice on correct administration

Shake well before use.
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 veterinary medicinal product should be administered pre-operatively as part of premedication. If additional analgesia is subsequently required, this may be achieved by administration of further dose(s) of buprenorphine or concomitant use of a suitable injectable NSAID.
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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after expiry date stated on the 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Vm 14966/3028

Pack sizes:
Box containing 1 glass vial of 10 ml

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:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release
LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26 , Pol. Ind. Can Parellada , Terrassa , 08228 Barcelona , Spain

17. Other information

Gavin Hall
Approved: 26 September 2025