ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 vial of 10 ml
Box with 5 vials of 10 ml
Box with 10 vials of 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprelab 0.3 mg/ml solution for injection for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Buprenorphine	0.3 mg
(equivalent to buprenorphine hydrochloride	0.324 mg)

3. PACKAGE SIZE

10 ml
5 x 10 ml
10 x 10 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.
Used by: ….

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

Labiana Life Sciences SA

14. MARKETING AUTHORISATION NUMBERS

Vm 32112/3003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprelab 0.3 mg/ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Buprenorphine	0.3 mg
(equivalent to buprenorphine hydrochloride	0.324 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.
Used by: ….

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Buprelab 0.3 mg/ml solution for injection for dogs and cats

2. Composition

Each ml contains:

Active substance:

Buprenorphine	0.3 mg
(equivalent to buprenorphine hydrochloride	0.324 mg)

Excipients:
Chlorocresol 1.35 mg

Clear and 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 Caesarian 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 product. The benefit/risk assessment for using the product should be made by the attending vet. 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 the section 'Dosage for each species, routes and methods 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. 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:

The excipient chlorocresol can cause hypersensitivity (allergic) reactions after skin contact. People with known hypersensitivity to chlorocresol should avoid contact with the veterinary medicinal product. In case of accidental skin contact, wash off immediately with water.

As buprenorphine has opioid activity, care should be taken to avoid self-injection or ingestion. Buprenorphine may be absorbed systemically on exposure to mucous membranes. The product, which is slightly acidic, may cause skin or eye irritation if contact occurs. Following eye, skin or mouth contact, wash the affected area thoroughly with water. Seek medical advice if irritation persists.
In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.
To the physician: In case of accidental self-injection the opioid antagonist naloxone may be used as antidote.

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.

The safety of the veterinary medicinal product has not been established during pregnancy. 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 (see below).

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.

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 tranquillisers, 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 cases 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.

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 3.5mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5mg/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:
<Not applicable>

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:

Uncommon (1 to 10 animals / 1,000 animals treated):	Ptyalism, bradycardia, hypothermia, agitation, dehydration and miosis. Respiratory depression.[1]
Rare (1 to 10 animals / 10,000 animals treated):	Hypertension, tachycardia. Sedation[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort[4], injection site pain.[3]

1- Refer to section Special precautions for safe use in the target species.
2- When used to provide analgesia, sedation may occur at dose levels higher than those recommended.
3- Resulting in vocalisation.
4- Local

Cats:

Common (1 to 10 animals / 100 animals treated):	Mydriasis. Behavioural disorders (restlessness, purring and excessive rubbing).[4]
Uncommon (1 to 10 animals / 1,000 animals treated):	Respiratory depression.[1]
Rare (1 to 10 animals / 10,000 animals treated):	Sedation.[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort[5], injection site pain.[3]

1- Refer to section Special precautions for safe use in the target species.
2- When used to provide analgesia, sedation may occur at dose levels higher than those recommended.
3- Resulting in vocalisation.
4- Will usually resolve within 24 hours.
5- Local

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: https://www.gov.uk/report-veterinary-medicine-problem

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

Intramuscular or intravenous use.

Species	Administration routes	Post-operative analgesia	Potentiation of the sedative
Dogs	intramuscular or intravenous	10 - 20 micrograms buprenorphine/ kg of b.w. (equivalent to 0.03-0.06 ml of veterinary medicinal product per kg of b.w.). Repeat, if necessary, after 3-4 hours with 10 micrograms of buprenorphine/ kg of b.w. or after 5-6 hours with 20 micrograms of buprenorphine per kg of b.w.	10-20 micrograms of buprenorphine/ kg of b.w. (equivalent to 0.03-0.06 ml of veterinary medicinal product per kg de b-w.)
Cats	intramuscular or intravenous	10 - 20 micrograms buprenorphine/ kg of b.w. (equivalent to 0.03-0.06 ml of veterinary medicinal product per kg of b.w.), repeated, if necessary, once, after 1-2 hours.	------

9. Advice on correct administration

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 preoperatively 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 response 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 dosing. The stopper cannot be broached more than 44 times.

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 the expiry date which is stated on the label or 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 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 32112/3003

Pack sizes:
Box with 1 vial of 10 ml
Box with 5 vials of 10 ml
Box with 10 vials of 10 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:

Labiana Life Sciences SA, Calle Venus 26, 08228 Terrassa (Barcelona) España

Local representatives and contact details to report suspected adverse reactions:

Accord Healthcare B.V.
Winthontlaan 200, Utrecht, 3526 KV,
Netherlands.
Telephone number: +44 (0) 208 901 3383
PVAnimal@accord-healthcare.com

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

17. Other information

Gavin Hall
Approved: 20 January 2025