

A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD CARTON/ SECONDARY PACKAGING**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic, 0.3mg/ml solution for injection for dogs and cats
Contains Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ampoules each 1 mL

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

For the relief of post-operative pain and sedation in dogs and for post-operative pain in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered by intramuscular injection only.
Post-operative pain: 10-20 micrograms per kg (0.3-0.6ml per 10kg). Repeated if necessary in cats, once, after 2 hours and in dogs after 3-4 hours with 10 microgram per kg or 5-6 hours with 20 microgram per kg.
Sedation: 10-20 micrograms/ kg (0.3-0.6ml per 10kg) in dogs.

8. WITHDRAWAL PERIOD

Not applicable

9. EXPIRY DATE

<EXP {month/year}>

10. SPECIAL STORAGE CONDITIONS

Protect from light.
Keep the container in the outer carton

11. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
Legal category
(Sch-III) POM-V

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

14. MARKETING AUTHORISATION NUMBER

Vm 15052/4080

15. MANUFACTURER’S BATCH NUMBER

Batch> <Lot> or <BN> {number}.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
TYPE I GLASS /PRIMARY PACKAGING**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic, 0.3mg/ml solution for injection for dogs and cats
Contains Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

i.m. (dogs and cats)

5. BATCH NUMBER

Batch> <Lot> or <BN>

6. EXPIRY DATE

<EXP {month/year}>

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

8. OTHER INFORMATION

Legal category
(Sch-III) POM-V
To be supplied only on Veterinary prescription

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Vetergesic, 0.3mg/ml solution for injection for dogs and cats
Contains Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:

LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26 , Pol. Ind. Can Parellada , Terrassa , 08228 Barcelona , Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetergesic, 0.3mg/ml solution for injection for dogs and cats
Contains Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Contains Buprenorphine 0.3 mg/mL (as buprenorphine hydrochloride, 0.324 mg/mL)

4. PHARMACOLOGICAL EFFECTS

Vetergesic is a trade name for buprenorphine hydrochloride, a potent long-acting analgesic acting at opioid receptor sites in the CNS. Buprenorphine exerts its analgesic effects via high-affinity binding to various sub-classes of opiate receptors, particularly μ , in the central nervous system.

Vetergesic is indicated for the relief of post operative pain and sedation in the dog or for post-operative pain in the cat.

Buprenorphine binds to opiate receptors with high affinity and high receptor avidity, such that its dissociation from the receptor is slow, as demonstrated by *in vitro* studies. This unique property of buprenorphine could account for its longer duration of activity when compared to morphine. Buprenorphine is rapidly absorbed after intramuscular injection in various animal species and in man. Pharmacological effects occur within 30 minutes after injection and peak effects are usually observed at about 1 – 1.5 hours. Following intramuscular injection to cats, the mean terminal half-life was 6.3 hours and the clearance was 23 mL/kg/min; however, there was considerable inter-cat variability in pharmacokinetic parameters.

Combined pharmacokinetic and pharmacodynamic studies in cats have demonstrated a marked hysteresis between plasma concentration and analgesic effect. Plasma concentrations of buprenorphine should not be used to formulate individual animal dosage regimens, which should be determined by monitoring the patient's response.

Buprenorphine is metabolised in the liver and in the major route of excretion is in the faeces, except in the rabbit where urinary excretion predominates.

5. ADVERSE REACTIONS

Salivation, bradycardia, hypothermia, agitation, dehydration and miosis can occur in the dog, and rarely hypertension and tachycardia.

Mydriasis and signs of euphoria (excessive purring, pacing, rubbing) commonly occur in cats and will usually resolve within 24 hours.

6. TARGET SPECIES

Dogs and cats

7. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Vetergesic should be injected intramuscularly

Species	Post-Operative Analgesia	Sedation
Dog	10-20 micrograms per kg (0.3-0.6ml per 10kg). repeat if necessary after 3-4 hours with 10 microgram per kg or 5-6 hours with 20 microgram per kg.	10-20 micrograms per kg (0.3-0.6ml per 10kg).
Cat	10 – 20 microgram per kg (0.3 – 0.6ml per 10kg), repeated if necessary, once, after 1 - 2 hours.	---

To ensure that analgesia is present during and immediately after surgery Vetergesic can be administered pre-operatively. If additional analgesia is subsequently required, this may be achieved by administration of further dose(s) of Vetergesic or concomitant use of suitable injectable NSAID.

An appropriately graduated syringe must be used to allow accurate dosing.

Vetergesic has been used successfully with a wide range of premedicant and anaesthetic agents including acepromazine, alphaxalone/alphadalone, atropine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone, and xylazine without any observed adverse effects.

When administered pre-operatively in conjunction with other premedicants such as acepromazine or medetomidine, it may be possible to reduce the amount of premedicant and also the amount of inhalational anaesthetic used.

8. SPECIAL STORAGE PRECAUTIONS

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

Protect from light.

Keep container in the outer carton.

9. SPECIAL WARNING(S)

Precautions:

Buprenorphine may occasionally cause respiratory depression; care should be taken in animals with impaired respiratory function or those being treated with drugs that can cause the condition.

Buprenorphine may cause some drowsiness which may be potentiated by other centrally acting agents, including tranquillisers, sedatives and hypnotics. It is recommended that Vetergesic should not be used in conjunction with morphine or other opioid-type analgesics, e.g. etorphine, fentanyl, pethidine, methadone, papaveretum or butorphanol.

Buprenorphine should be used with caution in animals with impaired liver function.

As animals treated with opioids may show variable responses, 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 use of an analgesic from an alternative class.

Safety has not been fully evaluated in clinically compromised cats e.g. those suffering from renal or hepatic dysfunction, cardiovascular disease or shock. Use in such cases should be based on the risk-benefit assessment of the veterinarian.

Repeat administration earlier than the recommended repeat interval suggested is not recommended.

Laboratory studies in rats and rabbits have produced no evidence of a teratogenic effects.

Although the reproduction studies in animals do not indicate a teratogenic risk, buprenorphine should be used with caution in pregnant animals.

Buprenorphine 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.

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 milk, care should be taken when administering it to lactating animals.

User Safety and Warnings

Wash hands/affected area thoroughly after any accidental spillage.

Care should be taken to avoid self-injection.

Following accidental self-injection or ingestion, seek medical advice taking the product literature with you.

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

Vetergesic does not contain an antimicrobial preservative. Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Overdosage

In cases of overdosage, supportive measures should be instituted, and, if appropriate, naloxone or respiratory stimulants may be used. Because of the prolonged duration of effect of buprenorphine in comparison to such drugs, they may need to be administered repeated or by continuous infusion.

10. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

11. OTHER INFORMATION

Presentation:

Vetergesic is presented in 1 ml ampoules, in boxes of five, as a sterile, clear, colourless, aqueous solution for injection.

Each 1 mL contains 0.3 mg/mL buprenorphine, (as buprenorphine hydrochloride 0.324 mg/mL).

Legal category

(Sch-III) POM-V

To be supplied only on Veterinary prescription

For animal treatment only

Keep out of the sight and reach of children

12. MARKETING AUTHORISATION NUMBER

Vm 15052/4080

Vetergesic is a Trade Mark.

Approved 20 October 2022

