PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buproxan Multidose 0.3 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Buprenorphine	0.3 mg/ml
Equivalent to Buprenorphine hydrochloride	0.323 mg/ml

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs, cats and horses (non-food producing).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs and cats: i.m., i.v.
Horses: i.v.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Not authorised for use in horses intended for human consumption.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

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

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 36408/5039

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass vial 10 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buproxan Multidose

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buprenorphine	0.3 mg/ml
equivalent to Buprenorphine hydrochloride	0.323 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Buproxan Multidose 0.3 mg/ml solution for injection for dogs, cats and horses

2. Composition

Each ml contains:
Active substances:

Buprenorphine	0.3 mg
equivalent to Buprenorphine hydrochloride	0.323 mg

Excipients:

Chlorocresol 1.35 mg

A clear, colourless to slightly yellowish solution.

3. Target species

Dogs, cats and horses (non food-producing).

4. Indications for use

Dogs:
Post-operative analgesia.
Potentiation of the sedative effects of centrally-acting agents.

Cats:
Post-operative analgesia.

Horses:
Post-operative analgesia in combination with a sedative.
Potentiation of the sedative effects of centrally-acting agents.

5. Contraindications

Do not administer by the intrathecal or peridural route.
Do not use pre-operatively for Caesarean section (see Special Warnings).
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:
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.
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 responsible veterinarian. Safety has not been fully evaluated in clinically compromised cats.
The safety of buprenorphine has not been demonstrated in dogs and cats less than 7 weeks of age, and in horses younger than 10 months old and weighing less than 150kg; therefore, use in such animals should be based on the risk-benefit 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 has not been investigated beyond 5 consecutive days of administration in cats or 4 separate administrations on 3 consecutive days in horses.
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.
Safety has not been evaluated in clinically-compromised horses. In horses, use of opioids has been associated with excitation, but effects with buprenorphine are minimal when administered in conjunction with sedatives and tranquilisers such as detomidine, romifidine, xylazine and acepromazine.
Ataxia is a known effect of detomidine and similar agents; consequently it may be seen after administration of buprenorphine with such substances.
Occasionally, ataxia may be marked. To ensure ataxic horses sedated with detomidine/buprenorphine do not lose their balance, they should not be moved or otherwise handled in any way that would compromise their stability.

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. Buprenorphine may be absorbed systemically on accidental 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, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Buprenorphine and the excipient chlorocresol can cause hypersensitivity (allergic) reactions after skin contact. People with known hypersensitivity to buprenorphine or chlorocresol should avoid contact with the veterinary medicinal product. In case of accidental skin contact, wash off immediately with water.

To the physician: In case of accidental self-injection the opioid antagonist naloxone may be used as antidote.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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 (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. Use only according 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 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, detomidine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, romifidine, 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
Studies in horses where buprenorphine has been administered with sedatives have shown very few effects at up to five times the recommended dosage, but when administered on its own it may cause excitement in pain-free-animals.

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.

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, Tachycardia,
Undetermined frequency (cannot be estimated from available data)	Increased salivation, Bradycardia, Hypothermia, Dehydration, Agitation, Miosis, Respiratory depression.

Cats:

Common (1 to 10 animals / 100 animals treated):	Mydriasis[1], Euphoria (excessive purring, pacing, rubbing)[1].
Undetermined frequency (cannot be estimated from available data)	Respiratory depression.

[1] usually resolve within 24 hours.

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Sedation[1], Colic.
Undetermined frequency (cannot be estimated from available data)	Respiratory depression, Excitation[2], Ataxia[2].

[1] when used to provide analgesia.
[2] when used in conjunction with sedatives or tranquillisers, excitation is normally minimal, but ataxia may occasionally be marked.

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:
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

Dogs and cats: Intramuscular (i.m.) or intravenous (i.v.) use.
Horses: Intravenous (i.v.) use

Target species	Route of administration	Post-operative Analgesia	Potentiation of sedation
Dog	Intramuscular or intravenous injection	10-20 µg/kg*, equivalent to 0.3 to 0.6 ml per 10 kg. For further pain relief, repeat if necessary after: - 3-4 hours with 10 µg/kg or - 5-6 hours with 20 µg/kg.	10-20 µg/kg, equivalent to 0.3 to 0.6 ml per 10 kg.
Cat	Intramuscular or intravenous injection	10-20 µg/kg*, equivalent to 0.15 to 0.3 ml per 5 kg. For further pain relief, repeat if necessary: - Once after 1-2 hours	-

Horse	Intravenous injection	10 µg/kg*, equivalent to 3.3 ml per 100 kg, 5 minutes after administration of an IV sedative. For further pain relief, repeat if necessary: once, after not less than 1 - 2 hours.	5 µg/kg*, equivalent to 1.7 ml per 100 kg, 5 minutes after administration of an IV sedative. The dose may be repeated if necessary after 10 minutes

*) The dosages expressed in µg/kg in the table above refer to buprenorphine (as hydrochloride). The kg in the table refers to body weight

9. Advice on correct administration

In dogs, sedative effects are present by 15 minutes after administration. In dogs, cats and horses analgesic activity may not develop fully until 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 used in horses, an intravenous sedative should be administered within five minutes prior to injection of buprenorphine.

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.

Due to the small volume to be administered, especially in small dogs and cats, extra care should be taken to use an appropriately graduated syringe to allow accurate dosing.
The stopper can be safely punctured up to 25 times.

10. Withdrawal periods

Not authorised for use in horses intended for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36408/5039

Pack size:

Cardboard box with 1 x 10 ml vial.

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:

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

17. Other information

POM-V

Gavin Hall

Approved: 04 March 2026