Veterinary
Medicines
Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

Date Created: April 2026

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Buproxan Multidose 0.3 mg/ml solution for injection for Dogs, Cats and Horses
Applicant	Alfasan Nederland B.V, Kuipersweg 9, 3449 JA Woerden, The Netherlands.
Active substance(s)	Buprenorphine
ATC vet code	QN02AE01
Target species	Dogs, cats, horses
Indication 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.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended
Date of conclusion of the procedure	04/03/2026

I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisation in Great Britain (GB), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended. The reference product is Vetergesic Multidose, 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses, authorised in GB since 13 February 2009 and marketed by Ceva Animal Health Ltd. The applicant claimed exemption from the requirement for bioequivalence studies in accordance with exemptions 7.1.a) and 7.1.b) of the Guideline on the Conduct of Bioequivalence Studies for Veterinary Medicinal Products, which was accepted.

Buproxan Multidose 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses contains 0.3 mg/ml buprenorphine as the active substance. The product is indicated for the treatment of post-operative analgesia in cats, and for post-operative analgesia and potentiation of the sedative effects of centrally-acting agents in dogs and horses.

The recommended doses of Buproxan for Dogs, Cats and Horses are detailed in the SPC. The product is approved for intramuscular or intravenous use in dogs and cats and intravenous use in horses.

The distribution category in GB is POM-V, same as the reference product.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains buprenorphine and the excipients chlorocresol, glucose, hydrochloric acid dilute, sodium hydroxide and water for injections.

The container/closure system consists of a colourless type I glass vial of 10 ml, with a type I fluorinated bromobutyl rubber stopper and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative is justified.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is buprenorphine, an established active substance in veterinary medicine described in the European Pharmacopoeia, supported by a Certificate of Suitability (CEP). The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

All excipients meet the requirements of the relevant European Pharmacopoeia (Ph. Eur.) monographs. The specifications for the packaging materials align with the European Pharmacopeia (Ph. Eur.) monograph.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for this type of dosage form.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

The shelf life of the veterinary medicinal product as packaged for sale is 2 years. The shelf life after first opening the immediate packaging is 28 days.

The product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Due to the legal basis of the application and as bioequivalence with the reference product was accepted, no new pharmacological data are required.

Buprenorphine is a potent, long-acting analgesic acting at opiate receptors in the central nervous system. Buprenorphine exerts its analgesic effect via high affinity binding to various sub-classes of opiate receptors, particularly μ in the central nervous system. 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 site is slow. This unique property of buprenorphine could account for its longer duration of activity when compared to morphine. Buprenorphine has little effect on gastro-intestinal motility.

Buprenorphine is rapidly absorbed after intramuscular injection in various animal species and man. Pharmacological effects may occur within minutes of administration and signs of sedation normally appear by 15 minutes. Analgesic effects in dogs and cats appear around 30 minutes. In pain-free horses, antinociceptive effects appear during the first 15 - 30 minutes.

The major route of excretion in all species except the rabbit is the faeces. Buprenorphine undergoes N-dealkylation and glucuronide conjugation by the intestinal wall and the liver and its metabolites are excreted via bile into the gastro-intestinal tract. Protein binding studies in rats have shown that buprenorphine is highly bound to plasma proteins, principally to alpha and beta globulins.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that when used as recommended, the product is not anticipated to pose an unacceptable risk to users.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- 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 this 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.

Environmental Safety

The applicant provided an environmental risk assessment in accordance with current guidelines. Assessment correctly stops at Phase I, with no Phase II required, as the product is for use in non-food producing animals only.

When used as recommended, the product is not anticipated to pose an unacceptable environmental risk.

Withdrawal Periods

The product is not authorised for use in horses intended for human consumption.

IV. CLINICAL DOCUMENTATION

Bioequivalence with the reference product was accepted, with exemptions from the requirement to conduct bioequivalence studies in accordance with sections 7.1.a) and 7.1.b) from the bioequivalence guideline, Guideline for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products. Therefore, due to the legal base of the application, no new clinical data were required.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that, when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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