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AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

PRODUCT SUMMARY

EU procedure number	FR/V/0520/001/DC
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 vetcode	QN02AE01
Target species	Dogs, cats and horses (non food-producing)
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.

Buproxan Multidose 0.3 mg/ml solution for injection for dogs, cats and horses	FR/V/0520/001/DC
ALFASAN NEDERLAND B.V.	DCP
Publicly available assessment report	

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP)	Vetergesic Multidose, 0.3 mg/ml Solution for Injection for Dogs, Cats and Horses
Marketing authorisation holder	CEVA ANIMAL HEALTH=
MS where the RP is or has been authorised	UK (NI)
Marketing authorisation number	Vm 15052/4081
Date of authorisation	13/02/2009

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains buprenorphine (as hydrochloride) at a concentration of 0.3 mg/ ml (quantitative) and chlorocresol, glucose, hydrochloric acid dilute, sodium hydroxide and water for injections as the excipients.

The container/closure system consists of glass vials fitted with rubber closures and a capsule.

The presence of preservative is justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

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

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substance is buprenorphine as hydrochloride, an established substance described in the European Pharmacopeia. 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.

Certificate of suitability issued by the EDQM has been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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 VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability tests

Stability data on the active substance have been provided in accordance with applicable European 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 European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

The in-use shelf life of the broached VMP is supported by the data provided. The recommendations in the product leaflet should be followed.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence to a reference VMP has been demonstrated, results of pharmacological and toxicological tests are not required.

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (generic veterinary medicinal product). According to Article 18, an application for a marketing authorisation for a generic veterinary medicinal product does not need to contain the documentation on toxicological studies.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because

The VMP will only be used in non-food animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

Pharmacology

Given the legal basis of this application and the claim of bioequivalence between candidate and reference products, the omission of pharmacodynamics/pharmacokinetics data is considered acceptable, as this information may be extrapolated from the reference product.

The bioequivalence was demonstrated according to the section 7.1 of the bioequivalence GL (EMA/CVMP/016/2000-Rev4*).

Tolerance in the target species of animals

No target animal tolerance data specific to the candidate product have been presented. However, as this is a generic application, the omission of product-specific target animal tolerance study data can be accepted.

B. Clinical trials

No clinical trials were performed.

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with the reference VMP has been demonstrated, results of clinical trials are not required.
The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.