MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE MEDICAMENTOS VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

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PRODUCT SUMMARY

EU procedure number	ES/V/0430/001/MR
Name, strength and pharmaceutical form	Buprelab Vet 0.3 mg/ml solution for injection for dogs and cats (SE, FI) Buprelab 0.3 mg/ml solution for injection for dogs and cats (ES, LV, LT, LU, BE, CY, FR, HU, RO) Buprelab (EE)
Applicant	Labiana Life Sciences S.A. Calle Venus 26, Can Parellada 08228 Terrassa (Barcelona) Spain
Active substance(s)	Buprenorphine hydrochloride
ATC vetcode	QN02AE01
Target species	Dogs, cats
Indication for use	Dogs: - Post-operative analgesia. - Potentiation of the sedative effects of centrally acting agents. Cats: - Post-operative analgesia.

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
Marketing authorisation holder	Ceva Santé Animale
MS where the RP is or has been authorised	Ireland
Marketing authorisation number EU procedure number	VPA10815/028/001
Date of authorisation	10-07-2009
Date of completion of the original mutual recognition procedure	18/10/2023
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	10/08/2021
Concerned Member States for original procedure	BE, CY, EE, FI, FR, HU, LT, LU, LV, RO, SE.

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)

2.A. Product description

The VMP contains 0.3 mg/ml Buprenorphine as active substance and the excipients: chlorocresol, glucose anhydrous, hydrochloric acid and water for injections.

The container/closure system is type I amber glass vial sealed with a chlorobutyl rubber stopper and aluminium capsule.

Details of the device with which the VMP will be used/administered are provided, as applicable.

The choice of the formulation is justified.

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

2.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.

2.C. Production and control of starting materials

The active substance is Buprenorphine, 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.

Scientific data and certificates of suitability issued by the EDQM have 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.

2.D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

2.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.

2.F. Stability tests

The stability of active substance is evidenced by the stability data presented by the CEP holder.

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.

2.G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

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

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that no different risks to the user are expected as results of its use and the warnings already set for the reference product are sufficient to ensure the safety of the user of veterinary medicinal product.

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. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals. The use of Buprenorphine Multidose 0.3 mg /ml Solution for injection for dogs and cats will not pose a risk of concern to the environment when used as recommended.

3.B. Residues documentation

n.a.

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.

4.A. Pre-Clinical Studies

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

4.B. Clinical trials

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

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.

None.