Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bupredine Multidose 0.3 mg/ml solution for injection for dogs, cats and horses
(AT, BE, CY, CZ, EL, ES, FR, HR, HU, LU, NL, PT, RO, SI, SK, UK)
Bupredine Multidose vet 0.3 mg/ml solution for injection for dogs, cats and horses
(EE, LT, LV, PL)
Bupredine vet 0.3 mg/ml solution for injection for dogs, cats and horses
(NO/SE/DK/IS)
Bupresol Multidose 0.3 mg/ml solution for injection for dogs, cats and horses
(DE)

Date Created: January 2016

PuAR correct as of 21/03/19 when RMS was transferred to NL. Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0549/001/DC
Name, strength and pharmaceutical form	Bupredine Multidose 0.3 mg/ml solution for injection for dogs, cats and horses
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater The Netherlands
Active substance(s)	Buprenorphine (as hydroxide) 0.3 mg Equivalent to 0.324 mg buprenorphine hydrochloride
ATC Vetcode	QN02AE01
Target species	Dogs, cats and horses
Indication for use	Post-operative analgesia in the dog and cat. Post-operative analgesia, in combination with sedation, in the horse. Potentiation of the sedative effects of centrally acting agents in the dog and horse.

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 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23rd September 2015.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Portugal, Poland, Romania, Slovakia, Slovenia, Spain, Sweden.

I. SCIENTIFIC OVERVIEW

This was a generic application submitted under Article 13 (1) of Directive 2001/82/EC as amended, for Bupredine Multidose 0.3 mg/ml solution for dogs, cats and horses. The reference product was Vetergesic Multidose 0.3 mg/ml Solution for Dogs, Cats and Horses, marketed in the UK since February 2009.

The product is intended to treat post-operative analgesia in the dog and cat, post-operative analgesia, in combination with sedation, in the horse and the potentiation of the sedative effects of centrally acting agents in the dog and horse.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto 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 (as hydrochloride) 0.3 mg, equivalent to 0.324 mg buprenorphine hydrochloride and the excipients chlorocresol, glucose monohydrate, hydrochloric acid, dilute, (for pH adjustment) and water for injections., The container/closure system consists of 5, 10, 20, 50 and 100 ml vials 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 are justified. The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European 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. The manufacturing method consists of three simple steps in which the active substance, preservative and glucose monohydrate are dissolved in water and the pH adjusted accordingly. The solution is made up to final weight with water, filtered, and then filled into vials, prior to heat sterilisation.

II.C. Control of Starting Materials

The active substance is buprenorphine hydrochloride, an established active substance described in the European Pharmacopoeia (Ph. Eur). 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. Certificates of Suitability were provided.

All excipients are monographed in the Ph. Eur.

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 proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product include those for appearance, colour, relative density, pH, extractable volume, identity of the preservative and the active substance and testing for impurities.

II.F. Stability

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. The re-test period for the active substance is 60 months for one supplier, and 48 months for the second. For the finished product, suitable data from three batches were provided, stored according to CVMP[3] guidelines. In-use shelf-life stability tests were performed on two batches stored in the 5 ml and 100 ml presentations.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 10, 20, 50 and 100 ml vials: 30 months. 5 ml vials: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

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

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, results of toxicological and pharmacological tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

[3] CVMP - The Committee for Medicinal Products for Veterinary Use.

III.A Safety Documentation

Environmental Safety

The product will only be provided to individual animals, therefore, the Environmental Risk Assessment stopped at Phase I. The SPC states:

- Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Withdrawal Periods

None. The product is not to be used in horses intended for human consumption.

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IV CLINICAL DOCUMENTATION

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.I. Pre-Clinical Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, pre-clinical efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.II. Clinical Documentation

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been established, field studies studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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(s) is favourable

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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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