ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats
(UK, BE, FR, IE, LU, NL, ES)

Buprenovet Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats
(AT, DE)

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0245/002/DC
Name, strength and pharmaceutical form	Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats
Applicant	Animalcare Limited Common Road, Dunnington, York, YO19 5RU UK
Active substance(s)	Buprenorphine (as buprenorphine hydrochloride)
ATC Vetcode	QN02AE01
Target species	Dogs and Cats
Indication for use	Post-operative analgesia in the cat and dog. Potentiation of the sedative effects of centrally acting agents in the dog.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	28 September 2011
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	Austria Belgium France Germany Ireland Luxembourg The Netherlands Spain

I. SCIENTIFIC OVERVIEW

Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats is authorised for use in post-operative analgesia in dogs and cats. The product can also be used for potentiation of the sedative effects of centrally acting agents in dogs. The product contains the active substance buprenorphine (as buprenorphine hydrochloride). In dogs, the dose rate is 10-20 micrograms per kg (0.3-0.6 ml per 10 kg) for post operative analgesia. For further pain relief, repeat if necessary after 3-4 hours with 10 microgram per kg or 5-6 hours with 20 microgram per kg. For potentiation of sedation, the dose rate is 10-20 micrograms per kg (0.3-0.6 ml per 10 kg). In cats, the dose rate is 10-20 microgram per kg (0.3-0.6 ml per 10 kg) for post-operative analgesia, repeated if necessary, once, after 1-2 hours. The route of administration is intramuscular or intravenous injection.

This application was made in accordance with Article 13 (1) of Directive 2001/82/EC as amended, for a generic application. The reference product is Vetergesic Multidose, marketed by Reckitt Benckiser Healthcare UK Ltd, which was authorised in the UK following a Mutual Recognition Procedure in April 2008. Vetergesic Multidose is part of the Global Marketing Authorisation for Vetergesic which was first authorised in April 1995.

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 and the slight 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 of the product was demonstrated according to the claims made in the SPC.

II. QUALITY ASPECTS

A. Composition

The product contains buprenorphine (as buprenorphine hydrochloride) 0.3 mg/ml as an active substance and excipients chlorocresol, glucose anhydrous, hydrochloric acid (for pH adjustment) and water for injection.

The product is packaged in 10 ml amber Type I glass vial with a bromobutyl rubber stopper and flip-off aluminium cap.

The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is justified.

[1] Summary of Product Characteristics

B. Method of Preparation of the Product

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 European guidelines.

C. Control of Starting Materials

The active substance buprenorphine as buprenorphine hydrochloride is the subject of monographs in the European Pharmacopoeia Ph. Eur.[2] and in the United States Pharmacopeia. The supporting data have been provided in the form of EDQM[3] CEP[4]. It is considered that the manufacturing process is adequately controlled and the active substance specifications have been suitably justified.

There are four excipients used in the formulation and each has been used previously in veterinary medicines. All excipients, except hydrochloric acid, have monographs in the Ph. Eur. and each complies with the requirements of the current edition of the Ph. Eur. The applicant has applied their own specification for hydrochloric acid. This is considered acceptable.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable

F. 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. The satisfactory validation data for the analytical methods have been provided.

[2] European Pharmacopoeia
[3] European Directorate for the Quality of Medicines and Healthcare
[4] Certificate of Suitability

G. Stability

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life. The shelf life of 18 months is justified when stored below 25ºC.

H. Genetically Modified Organisms

Not applicable

J. Other Information

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after opening the immediate packaging: 28 days

Special precautions for storage
Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.
Do not refrigerate or freeze

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

This application was made in accordance with Article 13 (1) of Directive 2001/82/EC as amended, for a generic application. The reference product is Vetergesic Multidose, marketed by Reckitt Benckiser Healthcare UK Ltd, which was authorised in the UK following a Mutual Recognition Procedure in April 2008. Buprecare Multidose and reference product Vetergesic Multidose are of the same pharmaceutical form and have the same qualitative and quantitative composition. As the dose rate and route of administration are also identical, the applicant claimed exemption from bioequivalence studies in accordance with paragrpah 4.b) of the Guidelines for the conduct of bioequivalence studies for veterinary medicinal products.

Pharmacological Studies

Since this generic application was submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, data on pharmacology and toxicology were not required.

User Safety

The following warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:

- Wash hands/affected area thoroughly after any accidental spillage.
- As buprenorphine has opioid-like activity, care should be taken to avoid accidental self-injection.
- In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Following eye contamination or skin contact, wash thoroughly with cold running water, seek medical advice if irritation persists.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment was required. The assessment concluded that no extensive exposure of the environment would occur due to use of the products, and this was acceptable

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Not applicable as the product is intended for administration to non-food species only.

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

Since this generic application was submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, data on this section were not required.

Tolerance in the Target Species of Animals

Since this generic application was submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, data on this section were not required.

IV.B Clinical Studies

Since this generic application was submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, the applicant has not submitted any data relating to efficacy. This is considered acceptable.

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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

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 product.

None