Austrian
Federal Office for
Safety in Healthcare
BASG

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Buprevet Multidose 0.3 mg/ml solution for injection for dogs and cats

and

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

AT/V/0013/001/DC

AT/V/0013/002/DX/001

Date: 07.01.2014

Last update: 29.11.2019

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BASG - Federal Office for Safety in Health Care

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Modules 1-3 reflect the scientific discussion for the approval of Buprevet Multidose 0.3 mg/ml solution for injection for dogs and cats and Buprevet 0.3 mg/ml solution for injection for dogs and cats (without the preservative chlorocresol). The procedures were finalised at 19/12/2013 and 12/10/2016 respectively.
For information on changes after this dates please refer to module 4.

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MODULE 1

PRODUCT SUMMARY

EU procedure numbers	AT/V/0013/001/DC AT/V/0013/002/DX/001
Names, strengths and pharmaceutical forms	Buprevet Multidose 0.3 mg/ml Solution for injection Buprevet 0.3 mg/ml solution for injection for dogs and cats
Applicant	Richter Pharma AG Feldgasse 19 AT – 4600 Wels
Active substance	Buprenorphine (as hydrochloride)
ATCvet code	QN02AE01
Target species	dogs and cats
Indication for use	DOG Post-operative analgesia. Potentiation of the sedative effects of centrallyacting agents. CAT Post-operative analgesia.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application)
Reference medicinal product	Vetergesic 0.3 mg/ml solution for injection for dogs and cats
Date of completion of the original decentralised procedure	Buprevet Multidose 0.3 mg/ml Solution for injection: 19/12/2013 Buprevet 0.3 mg/ml solution for injection for dogs and cats: 12/10/2016
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	UK

I. SCIENTIFIC OVERVIEW

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

The products are produced and controlled using validated methods and tests, which ensure the consistency of the products released on the market.

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

The products are safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

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

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

II. QUALITY ASPECTS

II.A Qualitative and quantitative particulars

Buprevet Multidose contains buprenorphine (as buprenorphine hydrochloride) as active substance and chlorocresol, glucose monohydrate, hydrochloric acid and water for injection as excipients.

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The container/closure systems are 10 ml amber glass vials, type I, with bromobutyl rubber stopper and aluminium cap.

Buprevet contains buprenorphine (as buprenorphine hydrochloride) as active substance and glucose monohydrate, hydrochloric acid, sodium hydroxide and water for injection as excipients.

The container/closure systems are 2 ml clear glass vials type II with a bromobutyl rubber stopper type I, coated and an aluminium cap.

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

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

II.B Method of Preparation of the Product

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

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

II.C Control of Starting Materials

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

There are four excipients used in the formulation and each has been used previously in veterinary medicines. All excipients have monographs in the Ph. Eur. and each complies with the requirements of the current edition of the Ph. Eur.

II.D Control on intermediate products (pharmaceuticals)

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 products.

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.

II.F Stability

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

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II.G Other Information

Shelf life

Shelf life of the veterinary medicinal products as packaged for sale:
Buprevet Multidose: 3 years. Buprevet:
30 months.

In-use shelf life

Shelf life after opening the immediate packaging:
Buprevet Multidose: 28 days.
Buprevet: 24 hours when stored at 2 - 8°C.

Special precautions for storage

Keep the vial in the outer carton in order to protect from light.
Buprevet Multidose: Do not refrigerate or freeze.
Buprevet: This product does not contain an antimicrobial preservative.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Since the applications are made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for generic veterinary medicinal products, data on pharmacodynamics and pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

Toxicological Studies

Since the applications are made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for generic veterinary medicinal products, this information is not required.

User Safety

Since the applications are made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, a detailed user safety is not required.

Nevertheless the applicant provided a satisfactory user risk assessment, identifying the risk to the users of the products and the potential routes of exposure. This showed that the most likely routes of exposure to the products would be via skin or eye contact or by accidental self-injection. In addition to the pharmacological effects which could occur in people in the event of accidental self-injection, it is known that chlorocresol (excipient in Buprevet Multidose) is an irritant. The risks have been identified and appropriate warnings are included in the SPC and product literature of Buprevet Multidose.

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

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Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The environmental risk assessment demonstrated that use of Buprevet multidose would not result in extensive environmental exposure. Warnings and precautions as listed on the SPC and product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

Since the applications are made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for generic veterinary medicinal products, this information is not required, as it has already been presented for the reference product.

Tolerance in the Target Species of Animals

Since the applications are made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for generic veterinary medicinal products, this information is not required, as it has already been presented for the reference product

IV.B Clinical Studies

Laboratory Trials

Since the applications are made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for generic veterinary medicinal products, this information is not required, as it has already been presented for the reference product.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossiers demonstrate that when the products are 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 products for humans and the environment is acceptable.

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MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPCs and package leaflets may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal products. The current SPCs are available on the Heads of Veterinary Medicines Agencies 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 products.

Significant changes

Summary of change **(Application number)**	**Approval date**
AT/V/0013/002/DX/001 Line Extension for Buprevet (without preservative chlorocresol)	12/10/2016
Both marketing authorisations were renewed unlimited.	7/11/2018
No further significant changes until today.	---

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