Bundesamt für Sicherheit
im Gesundheitswesen

BASG - Federal Office for Safety in Health Care

Traisengasse 5, A-1200 Vienna
www.basg.gv.at

AGES -
Austrian Agency for Health and Food Safety

Company:
Richter Pharma AG

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

and

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

AT/V/0008/001/DC

AT/V/0008/002/DX/001

Date: 10/10/2011

Last update: 20/09/2017

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Modules 1-3 reflect the scientific discussion for the approval of Bupaq *Multidose 0.3 mg/ml solution for injection for dogs and cats* and *Bupaq 0.3 mg/ml solution for injection for dogs and cats* (without the preservative chlorocresol). The procedures were finalised at 16/08/2011 and 21/06/2017 respectively.
For information on changes after this dates please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	AT/V/0008/001/DC AT/V/0008/002/DX/001
Name, strength and pharmaceutical form	Bupaq Multidose 0.3 mg/ml solution for injection for dogs and cats Bupaq 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)
ATC Vetcode	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 Medicines Agencies (veterinary) website (www.hma.eu).

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

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)
Date of completion of the original decentralised procedure	Bupaq Multidose 0.3 mg/ml solution for injection: 16/08/2011 Bupaq 0.3 mg/ml solution for injection for dogs and cats: 21/06/2017
Concerned Member States for procedure	Bupaq Multidose: BE, BG, CZ, DE, DK, EE, ES, FI, FR, HU, IE, IT, LT, LV, NL, NO, PL, PT, RO, SE, SK, UK Bupaq: DK, FR, NO, SE, UK

I. SCIENTIFIC OVERVIEW

Bupaq (Multidose) 0.3 mg/ml solution for injection for dogs and cats contains the active substance buprenorphine as buprenorphine hydrochloride. The product is authorised to be used in dogs and cats. The product is 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 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; the slight reactions observed are indicated in the SPC.
The product is 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 product 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

A. Composition

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

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

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

Bupaq 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 and its development is adequately described in accordance with the relevant European guidelines.

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 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.

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.

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

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.

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.

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 when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale:
Bupaq Multidose: 3 years. Bupaq:
30 months.

In-use shelf life
Shelf life after opening the immediate packaging:
Bupaq Multidose: 28 days.
Bupaq: 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.
Bupaq Multidose: Do not refrigerate or freeze.
Bupaq: This product does not contain an antimicrobial preservative.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on pharmacodynamics and

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

Toxicological Studies

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

User Safety

Since the application is 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 product and the potential routes of exposure. This showed that the most likely routes of exposure to the product would be via skin or eye contact or by accidental selfinjection. 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 Bupaq Multidose) is an irritant. The risks have been identified and appropriate warnings are included in the SPC and product literature of Bupaq Multidose.
Warnings and precautions as listed on the SPC and product literature are adequate to ensure safety to users of the product.

Ecotoxicity

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

Tolerance in the Target Species of Animals

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

IV.B Clinical Studies

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Laboratory Trials

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, 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 dossier demonstrate that when the product 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 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) 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.

Summary of change	**Approval date**
AT/V/0008/001/R/001 The marketing authorization of Bupaq Multidose was renewed unlimited.	02/06/2016
AT/V/0008/002/DX/001 Line Extension for Bupaq (without preservative chlorocresol).	21/06/2017
AT/V/0008/002/E/001 This marketing authorization was extended to other MS and therefore reassessed.	28/06/2018
No significant changes to date.	---

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."