Bundesamt für Sicherheit
im Gesundheitswesen

BASG - Federal Office for Safety in Health Care

AGES - Austrian Agency for Health and Food Safety
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Caniphedrin 20 mg Tabletten für Hunde,
Caniphedrin 50 mg Tabletten für Hunde

Date: 24/01/2018

Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH l Austrian Agency for Health and Food Safety Traisengasse 5 l 1200 Vienna l AUSTRIA l www.ages.at
DVR: 0014541 l Registration court: Vienna Commercial Court l Commercial register: FN 223056z l VAT No.: ATU 54088605

Modules 1-3 reflect the scientific discussion for the approval of Caniphedrin 20 mg Tabletten für Hunde, Caniphedrin 50 mg Tabletten für Hunde. The procedures were finalised on 20/12/2017. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU procedure number	AT/V/0016/001-2/DC
Name, strength and pharmaceutical form	Caniphedrin 20 mg Tabletten für Hunde, Caniphedrin 50 mg Tabletten für Hunde
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels Austria
Active substance(s)	EPHEDRINE HYDROCHLORIDE
ATCvet code	QG04BX90
Target species	Dogs
Indication for use	For the treatment of urinary incontinence caused by urethral sphincter mechanism incompetence, primarily urinary incontinence in ovariohysterectomised bitches.

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).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1), of Directive No 2001/82/EC as amended.
Reference medicinal product	Caniphedrin-20 resp. 50 ad us. vet. marketed by Selectavet Dr. Otto Fischer GmbH, Am Kögelberg 5, 83629 Weyarn/Holzolling, Germany
Date of completion of the original national procedure in DE:	29/10/1993
Concerned Member States for original procedure	None.

I. SCIENTIFIC OVERVIEW

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 (see 4.6: "adverse reactions")

The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC (see 4.5 "Special precautions for use").

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. Qualitative and quantitative particulars

The product contains:

Active substance: Ephedrine hydrochloride 20 mg (equivalent to 16.4 mg Ephedrine) and excipient(s):

Gelatine, potato starch, lactose monohydrate, talc, microcrystalline cellulose,

glycerol 85 %

Container/closure system: Heat-sealed blister pack, consisting of aluminium foil and a PVC foil with 10 tablets per blister. Cardboard box containing 10 blisters of 10 tablets each.

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 at a licensed manufacturing site.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is Ephedrine hydrochloride. 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 no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products (pharmaceuticals)

Not applicable.

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 has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance guideline with the ICH Q1A(R2) and EMEA/CVMP/846/99 Rev.1, respectively, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other

"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."

Information
None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of toxicological tests are not required.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, results of pharmacodynamic and pharmacokinetic tests are not required.

User Safety

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, a detailed user safety assessment is not required. The safety warnings are more extensive then the reference product to be in line with more recent authorisations.

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 accidental ingestion. The product is a prescription only medication and is administered to individual animals only. The excipients are commonly used and do not raise any toxicological concern. If the product is used as recommended in the SPC it is not expected to pose a risk for the user. The risks have been identified and appropriate warnings are included in the SPC and product literature.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be is used in non-food animals.

Conclusion:

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

Not applicable. The product is intended for use in non-food producing species only.

IV. CLINICAL ASSESSMENT (EFFICACY)

The applicant has confirmed that the reference product and the proposed generic product have an identical formulation and manufacturing process as well as the same manufacturer. Thus, the applicant has not provided data in support of Part IV.

A bioequivalence study has not been presented. The applicant applies for exemption from *in vivo* bioequivalence studies according to section 7.1(d) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2).

IV.A Pre-Clinical Studies

Pharmacology

This is a generic product with an identical formulation and manufacturing process to the reference product, and is therefore exempt from providing results from pre-clinical trials.

Tolerance in the Target Species of Animals

No data have been submitted concerning tolerance in the target species. The applicant states that this is a generic product with an identical formulation and manufacturing process to the reference product, and is therefore exempt from providing results from pre-clinical trials.

IV.B Clinical Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.

Laboratory Trials

As this is a generic application according to Article 13 with an identical formulation and manufacturing process to the reference product, laboratory studies are not required as they have already been presented for the reference product.

Field Trials

As this is a generic application according to Article 13, with an identical formulation and manufacturing process to the reference product, field studies are not required as they have already been presented for the reference product.

The product is efficacious when used according to the SPC.

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 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 product.

Significant changes

Summary of change **AT/V/0016/001-2/DC**	**Approval date**
No significant changes since marketing authorization.	20/12/2017