Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vetmedin 1.25 mg Chewable Tablets for Dogs
Vetmedin 2.5 mg Chewable Tablets for Dogs
Vetmedin 5 mg Chewable Tablets for Dogs
Vetmedin 10 mg Chewable Tablets for Dogs

AT/V/0006/001-004/DC

Date: 11/08/2016

Last update: 27/02/2024

Modules 1-3 reflect the scientific discussion for the approval of Vetmedin 1.25 mg / 2.5 mg / 5 mg Chewable Tablets for Dogs. The procedure was finalised at 19.11.2010. For information on changes after this date please refer to Module 4.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	AT/V/0006/001-003/DC
Name, strength and pharmaceutical form	Vetmedin 1.25 mg Chewable Tablets for Dogs Vetmedin 2.5 mg Chewable Tablets for Dogs Vetmedin 5 mg Chewable Tablets for Dogs
Applicant	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany
Active substance(s)	Pimobendan
ATC Vetcode	QC01CE90
Target species	Dog
Indication for use	For the treatment of canine congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid valve regurgitation).

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	The application for Vetmedin 1.25 mg and 10 mg Chewable Tablets for Dogs are hybrid applications in accordance with Article 13 (3) of Directive 2001/82/EC as amended by Directive 2004/28/EC. The applications for Vetmedin 2.5 mg and 5 mg Chewable Tablets for Dogs are generic applications in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC.
Reference medicinal product	Vetmedin 2.5 mg and 5 mg Capsules for Dogs marketed by Boehringer Ingelheim Vetmedica GmbH.
Date of completion of the original decentralised procedure	19.11.2010
Date product first authorised in the Reference Member State (MRP only)	N.A.
Concerned Member States for original procedure	Bulgaria, Cyprus, Czech Republic, Estonia, Greece, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia
Concerned Member States for repeat use procedure	Belgium, Finland, France, Ireland, Iceland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom

I. SCIENTIFIC OVERVIEW

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 in the target animals are indicated in the SPC.
The products are 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 products was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting the marketing authorisations.

The applicant has provided a detailed description of the pharmacovigilance system which fulfils the requirements of Directive 2001/82/EC, as amended. Based on the information provided the

applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

One tablet of the products "Vetmedin 1.25 mg/2.5 mg/5 mg Chewable Tablets for Dogs" contains pimobendan (1.25 mg, 2.5 mg or 5 mg) as active substance and the excipients povidone, lactose monohydrate, maize starch, croscarmellose sodium, citric acid (anhydrous), artificial powdered beef flavour, silica colloidal (anhydrous) and magnesium stearate.

The container/closure system is a HDPE screw-necked bottle with a polypropylene child-resistant closure. The particulars of the container and controls performed are provided and conform to the regulation.

The choice of the formulation is justified.

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

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

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

C. Control of Starting Materials

The active substance is pimobendan an established active substance 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.
A declaration was received from the applicant stating that the finished product is in compliance with the latest version of the CPMP/CVMP guideline on transmissible spongiform encephalopathies (EMEA/410/01 Rev. 3 of March 2011).

Excipients complying with the Ph. Eur. are microcrystalline cellulose, croscarmellose sodium and magnesium stearate. The natural meat flavour complies with the European Flavouring Directive 88/338/EEC.

D. Control on intermediate products

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 have been provided demonstrating compliance with the specification.

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.

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.

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As the application for Vetmedin 1.25 mg, 2.5 mg, 5 mg and 10 mg Chewable Tablets for Dogs were applications according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety and residue tests were not required.

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

A. Safety Testing

Pharmacological Studies

Since these are applications according to Article 13, and bioequivalence with reference products has been demonstrated, results of pharmacodynamic and pharmacokinetic tests are not required as they have already been presented for the reference products.

Toxicological Studies

Since these are applications according to Article 13, and bioequivalence with reference products has been demonstrated, results of toxicological tests are not required as they have already been presented for the reference products.

Observations in Humans

Since these are applications according to Article 13, and bioequivalence with reference products

has been demonstrated, data on observations in humans are not required as they have already been presented for the reference products.

User Safety

Since the applications for for a.m. medicinal products were made in accordance with Article 13(1) resp. (3) of Directive 2001/82/EC, as amended, and bioequivalence with the reference products has been established, a detailed user safety is not required.
Warnings and precautions as listed on the product literatures are adequate to ensure safety to users of the products.

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I because Vetmedin 1.25 mg, 2.5 mg, 5 mg and 10 mg Chewable Tablets for Dogs are recommended for individual treatment of 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.

B. Residues documentation

Residue Studies

As the products Vetmedin 1.25 mg, 2.5 mg and 5 mg Chewable Tablets for Dogs are only used for treatment of dogs (i.e. non-food producing animals), this part of the safety documentation is not relevant

IV. CLINICAL ASSESSMENT (EFFICACY)

Since these are applications according to Article 13, and bioequivalence with the reference products has been demonstrated, efficacy studies are not required. The efficacy claims for these products are equivalent to those of the reference products.

A. Pre-Clinical Studies

Pharmacology

Since these are applications according to Article 13, and bioequivalence with reference products has been demonstrated, results of pharmacodynamic and pharmacokinetic tests are not required as they have already been presented for the reference products.

Tolerance in the Target Species of Animals

Since these are extension applications according to Article 13, and bioequivalence with reference products has been demonstrated, results of tolerance studies are not required as they have already been presented for the reference products.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

B. Clinical Studies Laboratory Trials

Since these are applications according to Article 13, and bioequivalence with reference products has been demonstrated, data of laboratory studies are not required as they have already been presented for the reference products.

Field Trials

Since these are applications according to Article 13, and bioequivalence with reference products has been demonstrated, data of field trials are not required as they have already been presented for the reference products.

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 (Application number)	Approval date
Repeat Use Procedure (AT/V/0006/001-003/E/001)	26.09.2012
Changes in SPC after Repeat Use Procedure (AT/V/0006/001-003/II/003)	04.12.2012
Addition of new strength – 10 mg chewable tablet (AT/V/0006/004/DX/001)	25.09.2013
Extension of shelf life – 2 to 3 years (AT/V/0006/001-003/IB/009)	15.10.2014
Change in the SPC following assessment of the same change for the reference product – change in the indication (AT/V/0006/001-004/IB/011)	04.02.2015
This marketing authorization was renewed unlimited. (AT/V/0006/001-004/R/001)	30.10.2015
New indication: treatment of dogs with myxomatous mitral valve disease (MMVD) (AT/V/XXXX/WS/003)	20.07.2017
Finished Product, Container Closure System, change of cap dimensions (AT/V/0006/001-004/IA/023)	03.06.2020
*** No significant changes since ***	