Institute for State Control of Veterinary Biologicals and Medicines
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Czech Republic
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Miziverm 2.5 mg/25 mg tablets for small dogs and puppies

Miziverm 12.5 mg/125 mg tablets for dogs

PRODUCT SUMMARY

EU procedure number	CZ/V/0203/001-002/DC
Name, strength and pharmaceutical form	Miziverm 2.5/25 mg tablets for small dogs and puppies; Miziverm 12.5/125 mg tablets for dogs
Applicant	Bioveta a.s., Komenskeho 212/12, 683 23, Ivanovice Na Hane, Czech Republic
Active substance(s)	Milbemycin oxime Praziquantel
ATC vet code	QP54AB51
Target species	Dogs
Indication for use	For dogs with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, eyeworm, lungworms and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease/angiostrongylosis is indicated at the same time.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Milbemax 2.5 mg/25 mg tablets for small dogs and puppies and Milbemax 12.5 mg/125 mg tablets for dogs
Marketing authorisation holder	Elanco GmbH
MS where the RP is or has been authorised	CZ - RMS
Marketing authorisation number EU procedure number	96/036/05-C; 96/035/05-C FR/V/0135/001; FR/V/0135/002
Date of authorisation	09/09/2005
Date of completion of the original decentralised procedure	26/11/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	N.A.
Concerned Member States for original procedure	BG, EL, HU, LT, LV, MT, PL, RO, SK
Concerned Member States for subsequent recognition procedure	N.A.
Withdrawn CMS during original decentralised recognition procedure	N.A.

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

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

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMPs contains Milbemycin oxime and Praziquantel as active substances. Two strengths of tablets are available containing:

	Tablets 2.5/25 mg	Tablets 12.5/125 mg
Milbemycin oxime	2.5 mg	12.5 mg
Praziquantel	20 mg	125 mg

The following excipients are included in the formulation:

- Cellulose, microcrystalline
- Croscarmellose sodium
- Potato starch
- Poultry aroma with yeast
- Povidone 25
- Lactose monohydrate
- Silica, colloidal anhydrous
- Magnesium stearate

The tablets are individually packed in bags made of PET/Al/LDPE foil. The bags are placed in paper box. The pack size is 2 and 50 tablets in box.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at licensed manufacturing sites.

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

C. Production and control of starting materials

The active substances Milbemycin oxime and Praziquantel are established active substances described in the European Pharmacopeia. The active substances are 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.

Certificates of suitability issued by the EDQM have been provided.

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

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

F. Stability tests

Retest periods are declared on the respective CEPs for each active substance.

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

G. Other information

In vivo bioequivalence study is presented between the originator product and generic (strength 12.5/125 mg). In-vitro equivalence is then confirmed by dissolution studies for the lower strength 2.5/25 mg.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, results of pharmacological and toxicological tests are not required.

A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline and warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

Warnings and precautions as listed on the product literature are the same as those of the reference veterinary medicinal product and are adequate to ensure safety of the product to the environment.

B. Residues documentation

Not applicable. The product is intended for non-food-producing animals (for dogs).

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

No pre-clinical studies were performed.

Development of resistance and related risk in animals

The bibliography provided suggests that there is a potential for anthelmintic resistance to milbemycin oxime and praziquantel; however, the exact mechanisms of resistance for both are still unknown.

Adequate warnings and precautions appear on the product literature.

Tolerance in the target species of animals

The applicant has submitted an in vivo bioequivalence study comparing their test formulation of the higher strength (12.5/125 mg tablets) with the reference product in the target species dogs.
In the case of the lower strength of Miziverm (2.5/25 mg), for the purposes of the marketing authorisation procedure, a comparison (chemical equivalence) that verified the full quantitative conformity of the two strengths of the products has also been provided for the Part II.

B. Clinical trials

No clinical trials were performed.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

None