Institute for State Control of Veterinary Biologicals and Medicines
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(Reference Member State - CZ)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Helminthex 425.45 mg/g oral paste for horses (AT, CZ, IT, LV, PL, PT)
Helminthex oral paste for horses (FR)

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/0146/001/DC
Name, strength and pharmaceutical form	Helminthex 425 mg/g oral paste for horses (AT, CZ, IT, LV, PL, PT) Helminthex oral paste for horses (FR)
Applicant	Pharmanovo Veterinärarzneimittel GmbH Liebochstrasse 9, 8143 Dobl, Austria
Active substance(s)	Pyrantel embonate
ATC Vetcode	QP52AF02
Target species	Horses
Indication for use	Treatment of infections with adult intestinal stages of large strongyles (*S.vulgaris, S. edentatus, S.equinus*), small strongyles (*Triodontophorus spp., Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp.*,), pinworms (*Oxyuris equi*) and large horse roundworm (*Parascaris equorum*).

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 2001/82/EC, as amended.
Date of completion of the original decentralised procedure	17/04/2019
Date product first authorised in the Reference Member State (MRP only)	NA
Concerned Member States for original procedure	AT, FR, IT, LV, PL, PT

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.
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. Qualitative and quantitative particulars

The product contains 425.45 mg of pyrantel embonate (which is equivalent to 147.57 mg of pyrantel) per 1 g and excipients sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, refined soya-bean oil, sorbitan oleate, polysorbate 80, propylene glycol and water for injection.

The container/closure system consists of low density polyethylene (LDPE) syringe with a graduated LDPE piston, a LDPE cap and a polystyrene plunger.

The choice of the presence of preservatives 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 product is manufactured fully in accordance with the principles of good manufacturing practice at 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 pyrantel embonate, an established substance described in the European Veterinary 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.

Scientific data and a certificate 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 product.

D. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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<s> 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.

The in-use shelf-life of the product is supported by the data provided.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to 13(1) of Directive 2001/82/EC as amended results of safety tests are not required.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. The product presents the same risks to the user as the reference product; therefore the similar warnings are included on the SPC and product literature. These precautions are adequate to ensure safety to users of the product.

- People with known hypersensitivity to pyrantel or any excipients should avoid contact with the veterinary medicinal product.
- Avoid direct contact with skin, mucosa or eyes.
- In case of contact with skin, mucous membranes or eyes, rinse intensively with water.
- Do not smoke, eat or drink when handling the product.
- Wash hands after use.

Environmental Risk Assessment

An Environmental Risk Assessment (ERA) was conducted in accordance with VICH and CVMP guidelines.

Phase I:

The product is an oral paste for use in horses.

The initial predicted environmental concentration in soil (PECsoil, initial) was less than 100 µg/kg but the product is antiparasitics and therefore the potential for pyrantel embonate to adversely affect the environment was anticipated. To avoid direct excretion of pyrantel residues from treated horses on pasture the applicant proposed mitigation measure to be included in product literature and submitted sufficient scientific evidence to support safety warning to keep horses indoors during administration of the product and for three days after treatment.

The following mitigation measure was included on the SPC and product literature.

- In order to avoid direct release of pyrantel to the environment, horses should not be turned out onto pasture within 3 days of treatment.

III.B Residues documentation

Residue Studies

The applicant has submitted the generic application in accordance with Article 13(1) of Directive 2001/82/EC, as amended. No residue depletion studies were required at this case.

MRLs

According to the Annex I of Commission Regulation (EU) No. 37/2010 – following MRLs have been established for the active substance:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Pyrantel embonate	Not applicable	*Equidae*	No MRL required	Not applicable	No entry	No entry

Withdrawal Periods

Based on information above, the following withdrawal periods were approved:

Withdrawal period(s):
Meat and offal: 1 day.
Not authorised for use in mares producing milk for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of 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

None