IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Curofen 50 mg/g Oral Powder for Pigs

"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."

PRODUCT SUMMARY

EU Procedure number	IE/V/0348/001/DC
Name, strength and pharmaceutical form	Curofen 50 mg/g oral powder for pigs
Active substance(s)	Fenbendazole
Applicant	Univet Limited Tullyvin Cootehill County Cavan Ireland
Legal basis of application	Generic application in accordance with Article 13.(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	23/09/2015
Target species	Pigs
Indication for use	For the treatment of benzimidazole susceptible mature and immature (L_4) forms of the following nematodes of the gastrointestinal and respiratory tracts of pigs: *Hyostrongylus rubidus* (red stomach worm) *Oesophagostomum* spp. (nodular worms) *Ascaris suum* (eel worm) *Trichuris suis* (whip worm) *Metastrongylus apri* (Lungworm)
ATCvet code	QP52AC13
Concerned Member States	BE, CY, DK, EL, ES, FR, HU, IT, NL, PL, PT, RO, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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

II QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 50 mg/g fenbendazole and the excipients glucose monohydrate and colloidal anhydrous silica. The container/closure system consists of 200 g and 1kg bags composed of clear low density polyethylene (LDPE) laminated with metallised polyester, and 1 kg bags composed of clear low density polyethylene (LDPE).

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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is fenbendazole, 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 has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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 has 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 has 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

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

This application was for Curofen 50 mg/g oral powder for pigs, containing fenbendazole as active substance. The application was submitted using the decentralised application procedure in the RMS and thirteen CMSs. The application was for a generic product and was submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended.

The reference product cited by the applicant was Curazole 5% w/w Oral Powder for Pigs first authorised in the RMS on 29/07/2011. The marketing authorisation for the reference product is also held by the applicant.

Given that this was a generic application referring to the marketing authorisation of a reference product held by the same company (so-called auto-generic application) and manufactured by the same finished product manufacturer, the candidate formulation was accepted as being identical to that of the reference product.

Further, the candidate formulation will be administered to the same target species using the same posology and route of administration already approved for the reference product.

Given the essential similarity with the reference product, an exemption from the requirement to demonstrate *in-vivo* bioequivalence was accepted.

Pharmacological Studies

As this was a generic application submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended and bioequivalence with the reference product was accepted, the applicant was not required to provide the results of pharmacological studies.

Toxicological Studies

As this was a generic application submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended and bioequivalence with the reference product was accepted, the applicant was not required to provide the results of toxicological studies.

User Safety

The applicant provided a user safety assessment. As the composition of the candidate formulation is identical to that of the reference product and is to be administered to pigs using the same posology and route of administration, it was accepted that any potential risk to the user from handling, storing, administering or disposing of the candidate formulation will not differ (i.e. won't be greater) than that which already exists for the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I

The applicant provided a Phase I environmental risk assessment. Based on the results of the Phase I assessment, it was concluded that a Phase II assessment was not required as all predicted environmental concentrations of fenbendazole, following administration to the target species, were determined to be lower than the value required to trigger a Phase II assessment.

Conclusion

Based on the data provided, it was accepted that the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when stored, handled, administered and disposed of in accordance with the recommendations included in the SPC.

III.B Residues Documentation

Residue Studies

No residue study data was provided. Given that this was a generic application referring to the marketing authorisation of a reference product held by the same company (so-called auto-generic application) and manufactured by the same finished product manufacturer, the candidate formulation was accepted as being identical to that of the reference product and consequently, bioequivalence between candidate and reference product formulations can be assumed.

It was concluded that residue depletion data was not required and that the depletion of residues in the target species when administered the candidate formulation will be the same as that when administered the reference product.

MRLs

Fenbendazole is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All ruminants, Porcine, Equine	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg	Muscle Fat Liver Kidney	For porcine species the fat MRL relates to 'skin and fat in natural proportions'.	Antiparasitic agents/Agents against endoparasites.
		All ruminants	10 µg/kg	Milk		

Withdrawal Periods

Given that the candidate formulation is identical to that of the reference product, both products are manufactured by the same finished product manufacturer and are to be administered using the same posology and route of administration in the same target species, it was concluded that no difference in depletion of residues in the target animal is to be expected.

Consequently, it was accepted that the 6 days withdrawal period for meat and offal approved for the reference product, is also applicable to this generic product and is considered adequate to ensure consumer safety.

IV CLINICAL ASSESSMENT (EFFICACY)

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

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

No target animal tolerance studies were conducted. Given that this was a generic application referring to the marketing authorisation of a reference product held by the same company (so-called auto-generic application) and manufactured by the same finished product manufacturer, the candidate formulation was accepted as being identical to that of the reference product.

Further, the candidate formulation will be administered to the same target species using the same posology and route of administration already approved for the reference product.

Consequently, it was concluded that no difference in tolerance in the target animal is to be expected between candidate and reference product formulations. The omission of target animal tolerance data was therefore accepted.

Resistance

As the candidate formulation was accepted as being identical to that of the reference product and will be administered to the same target species using the same posology and route of administration, it was accepted that no difference is to be expected between candidate and reference products in terms of risk for resistance development.

Suitable warnings and precautions are included in the product literature to ensure effective use of the product.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, clinical studies and field trials were 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 benefit/risk profile for the target species is favourable and the quality, safety and efficacy of the product are acceptable.

VI POST-AUTHORISATION ASSESSMENTS

None.