IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Ecomectin 6 mg/g Oral Powder for pigs

PRODUCT SUMMARY

EU Procedure number	IE/V/0235/001/DC
Name, strength and pharmaceutical form	Ecomectin 6 mg/g Oral Powder for pigs
Active substance(s)	Ivermectin
Marketing Authorisation Holder	ECO Animal Health Europe Limited, (22693), 6th Floor, South Bank House, Barrow Street, Dublin 4, D04 TR29, 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	27 January 2010
Target species	Pigs
Indication for use	Treatment of nematode or arthropod infections
ATCvet code	QP54AA01
Concerned Member States	BE, DE, DK, LU, IT, NL, PL

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

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars
The product contains 6 mg/g ivermectin and the excipients butylhyrdoxyanisole, propyl gallate and polyoxyl hydrogenated castor oil.
The container/closure system consists of a 333 g aluminium foil sachet and a 5 kg bag consisting of a primary aluminium foil bag placed inside a woven polypropylene/bleached paper laminate bag.The aluminium foil is the same as that used in the 333 g sachet.

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 ivermectin, 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.

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

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
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 have 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
Pharmacological Studies
The present application (Ecomectin 6 mg/g oral powder for pigs) relates to a new pharmaceutical form of an existing Article 13(1) (generic) application, Ecomectin 6 mg/g premix for medicated feedingstuff for pigs, which was authorised via DCP in 2008 (Procedure No. IE/V/0195/001/DC with Day 210 of 30/01/2008).

The Oral Powder is intended for administration to individual animals with an amount of feed for immediate consumption.

The oral powder is identical in all respects to the authorised premix, with the exception of the way in which it is administered to the target animals. Consequently, no Part III or Part IV data are provided. The Applicant simply cross refers to Parts III and IV of the dossier for Ecomectin 6 mg/g premix for medicated feedingstuff for pigs (IE/V/0195/001/DC). Given that the formulations of the Oral Powder and the Premix are identical, it can be concluded that the systemic effects of the two products in respect of safety and residues will be the same. No additional information in support of safety of the Oral Powder is required.

With the exception of the method of administration (detailed in section 4.9), the proposed text for sections 4 and 5 of the SPC (indications, contraindications, precautions for use, other warnings, user warnings, dose rate, withdrawal periods) is that same as that included in the authorised SPC of the Premix product.

User Safety
It is accepted that warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment
In accordance with the CVMP 'Reflection paper on the implementation of Directive 2001/82/EC, as amended, in respect to the assessment of environmental risks of veterinary medicinal products' (EMEA/CVMP/182112/2006-Final) adopted by the CVMP on 11/02/09 '…no ERA [for extension applications] would be necessary if it can be justified that there is no increase of environmental exposure.'

Given that the proposed conditions of use of the Oral Powder product (in terms of indications, posology) are identical to those of the authorised Premix product, an increase in environmental exposure associated with the use of the Oral Powder product, relative to the authorised Premix product, is not to be expected. It is accepted that cross reference to the existing ERA for the Premix product is appropriate.

III.B Residues Documentation
As advised above, given that the formulations of the Oral Powder and the Premix are identical, it can be concluded that the systemic effects of the two products in respect of safety and residues will be the same. Therefore, it is accepted that the authorised withdrawal period for the Premix product can be applied to the Oral Powder.

Based on the above, a withdrawal period of 12 days for meat in pigs is justified.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies
The present application (Ecomectin 6 mg/g oral powder for pigs) relates to a new pharmaceutical form of an existing Article 13(1) (generic) application, Ecomectin 6 mg/g premix for medicated feedingstuff for pigs, which was authorised via DCP in 2008 (Procedure No. IE/V/0195/001/DC with Day 210 of 30/01/2008).

The Oral Powder is intended for administration to individual animals with an amount of feed for immediate consumption.

The oral powder is identical in all respects to the authorised premix, with the exception of the way in which it is administered to the target animals. Consequently, no Part III or Part IV data are provided. The Applicant simply cross refers to Parts III and IV of the dossier for Ecomectin 6 mg/g premix for medicated feedingstuff for pigs (IE/V/0195/001/DC). Given that the formulations of the Oral Powder and the Premix are identical, it can be concluded that the systemic effects of the two products in respect of efficacy will be the same. No additional information in support of efficacy specifically of the Oral Powder is required.

With the exception of the method of administration (detailed in section 4.9), the proposed text for sections 4 and 5 of the SPC (indications, contraindications, precautions for use, other warnings, dose rate, withdrawal periods) is that same as that included in the authorised SPC of the Premix product and can be accepted.

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.

VI. 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 HPRA website.

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.

Changes:
None.