IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Flubendazole Elanco 50 mg/g oral powder for pigs

PRODUCT SUMMARY

EU Procedure number	IE/V/0292/001/DC
Name, strength and pharmaceutical form	Flubendazole Elanco 50 mg/g oral powder for pigs
Active substance(s)	Flubendazole
Marketing Authorisation Holder	Elanco GmbH Heinz-Lohmann-Str.4 27472 Cuxhaven Germany
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of procedure	21/12/2012
Target species	Pigs
Indication for use	Treatment of helminthiasis due to mature and immature stages of the following nematodes of the gastro-intestinal tract: *Ascaris suum,* (large roundworm), *Hyostrongylus rubidus,* (red stomach worm), *Oesophagostomum dentatum,* (nodular worm), *Trichuris suis,* (whipworm), Strongyloides *ransomi* (threadworm) (adult). Flubendazole is ovicidal.
ATCvet code	QP52AC12
Concerned Member States	FR, 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 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 flubendazole 50mg/g and the excipients titanium dioxide (E171), sodium laurilsulfate and lactose monohydrate.The product (600 g) is presented in a polypropylene container with a low density polyethylene (LDPE) snap-on closure.
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 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 flubendazole, an established 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 have been provided.
Batch analytical data from the proposed production sites 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 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)

III.A Safety Testing

Pharmacological Studies

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). It was confirmed that the formulation and manufacturing process for the product is identical to that of the reference product. As a result it was accepted that the product was bioequivalent to the reference product, Flubenol 5% w/w oral powder for pigs (VPA 10545/034/001).

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of pharmacological tests are not required.

The pharmacological aspects of this product reflect those of the reference product.

Toxicological Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of toxicological tests are not provided.

User Safety

It was accepted that the product will not pose any greater risk to the user than the risks associated with use of the reference product Flubenol 5% w/w oral powder for pigs.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment was required. No warnings are therefore required.
Precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues Documentation

Residue Studies

The product that is the subject of the present application is identical in every respect (composition, manufacturing process) to the reference product. On this basis it was assumed that depletion of residues from target tissues will be identical.
Consequently, exemption from the requirement to present confirmatory residue data was justified and the authorised withdrawal period for the reference product can be applied to the generic product.

MRLs

Flubendazole is listed in Table 1 of the Annex of Commission Regulation (EU) No. 37/2010 (O.J. 20.1.2010, L15/33).The marker substance is Sum of flubendazole and (2-amino 1H-benzimidazol-5-yl) (4fluorophenyl) methanone.
MRLs are listed below:

	Porcine
Muscle	50 µg/kg
Liver	400 µg/kg
Kidney	300 µg/kg
Fat/ skin	50 µg/kg

Withdrawal Periods

Based on the data provided above, a withdrawal period of 7 days for meat in pigs is justified.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

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

Resistance

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, 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 benefit/risk 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.