IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Quinox 60.6 mg/g Premix for Medicated Feeding Stuff for Cattle and Sheep

PRODUCT SUMMARY

EU Procedure number	IE/V/0589/001/DC
Name, strength and pharmaceutical form	Quinox 60.6 mg/g Premix for Medicated Feeding Stuff for Cattle and Sheep
Active substance(s)	Decoquinate
Applicant	Huvepharma NV Uitbreidingstraat 80 2600 Antwerpen Belgium
Target species	Sheep (lambs), cattle (calves)
Indication(s) for use	For the treatment and metaphylaxis of coccidiosis in lambs and calves during coccidial challenge. The presence of the disease in the group/flock must be established before the product is used.
ATCvet code	QP51BX04

SUMMARY OF ASSESSMENT

Legal basis of original application	Generic application in accordance with Article 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP) Marketing authorisation holder Marketing authorisation number Date of authorisation	Deccox 60.6 g/kg Premix for Medicated Feeding Stuff Phibro Animal Health VPA25497/002/001 01/10/1989
Date of completion of the original decentralised procedure	13/05/2026
Concerned Member States for original procedure	BE, CY, CZ, EL, ES, HU, IT, NL, PT, SK, UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (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 relevant articles of Regulation (EU) 2019/6. 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), the labelling and package leaflet for this product are available in the Union Product Database (UPD).

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. Product description

The product contains decoquinate (60.6 mg) and the excipients silica colloidal hydrated, soya bean oil refined and wheat flour.
The container/closure system is standard for this dosage form and is described in the SPC.

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 Description of the manufacturing method

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 Production and control of starting materials

The active substance is an established active substance. 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.

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 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 tests

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 Tests

Pharmacological Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6, and essential similarity to a reference VMP has been demonstrated, results of pharmacological tests are not required.

Toxicological Studies

As this is a generic application according to Article 18 of Regulation (EU) 2019/6, and essential similarity to a reference VMP has been demonstrated, results of toxicological tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that this veterinary medicinal product may be harmful in cases of dermal contact including hand-to-mouth contact.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I and Phase II environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

A Phase II ERA is required as the Phase I assessment showed that the worst-case initial predicted environmental concentration in soil (PECsoil initial = 159.9 µg/kg) is greater than 100 µg/kg and no mitigations exist that alter the PECsoil.

Phase II

A Phase II data set was provided according to the requirements of the CVMP/VICH guideline GL38 and the CVMP guideline on the Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-Rev.1), The data were considered to be complete and acceptable.

Physical-chemical properties		
Study type	**Test protocol**	**Result**
Water solubility	OECD 105	<0.04 mg/L at pH 5, 7 and 9 at 20°C
Dissociation constants in water pKa	OECD 112	Could not be determined due to insolubility of decoquinate in water.
n-Octanol/Water Partition Coefficient $logP_{ow}$	OECD 123	$logK_{ow}$ at pH 5 = >5.218 $logK_{ow}$ at pH 7 = >5.215 $logK_{ow}$ at pH 9 = >5.176

Environmental fate		
Soil Adsorption/Desorption	OECD 106	Koc = 482,229
Aerobic and Anaerobic Transformation in Soil	OECD 307	$DT_{50,\ 20°C}$ = 129.1 days $DT_{50,\ 12°C.\ geo.\ mean\ of\ 4x\ soils}$=276 days

Effect studies				
Study type	**Test protocol**	**Endpoint**	**Result**	**Unit**
Algae growth inhibition test/*Pseudokirchneriella subcapitata*	OECD 201	EC50	12.99	µg/l
Daphnia sp. immobilisation	OECD 202	EC50	>12.23	µg/l
Daphnia magna, reproduction	OECD 211	NOEC	>35.59	µg/l
Fish, acute toxicity/*Oncorhynchus mykiss*	OECD 203	LC50	>39.2	µg/l
Soil micro-organisms: nitrogen transformation test (100 days)	OECD 216	% effect	No effect up to 10 mg/kg dry soil	
Terrestrial Plants, growth test	OECD 208	EC10	245.2	mg/kg
Earthworm reproduction	OECD 222	NOEC	500	mg/kg
Bioaccumulation in fish/*Oncorhynchus mykiss*	OECD 305 Type: bioconcentration	BCF (lipid-normalised growth-corrected kinetic)	65	l/kg

Risk characterisation

The Predicted Environmental Concentration (PEC) for each compartment was calculated in accordance with VICH guideline GL6 and the CVMP guideline on the Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-Rev.1).

Using the assessment factors (AF) in these VICH guidelines, predicted no effect concentrations (PNEC) were calculated and compared with the PEC values. This results in a risk quotient (RQ) for each compartment as follows:

Compartment	**PNEC**	**PEC**	**RQ**
Surface water *Algae* *Aquatic invertebrates* *Fish*	 0.1299 µg/l 0.01223 µg/l 0.0392 µg/l	0.0009 µg/l	 < 1 < 1 < 1
Soil microorganisms: Nitrogen transformation test	<25% difference in N transformation	NA	NA
Soil *Earthworms* *Terrestrial plants*	 50,000 µg/kg 2452 µg/kg	186.13 µg/kg	 < 1 < 1

The risk characterisation resulted in risk quotient below 1 for the surface water and soil compartments indicating that the product will not pose a risk to those compartments when used as recommended. No risk to the groundwater compartment was identified.

PBT Assessment

An assessment of the compound in terms of potential for Persistence, Bioaccumulation and Toxicity (PBT) for the environment or whether it may be considered as being very Persistent and very Bioaccumulative (vPvB) was performed.

PBT-assessment			
Parameter	**Result relevant for conclusion**		**Conclusion**
Bioaccumulation	BCF	65 l/kg	not B
Persistence	$DT_{50,\ compartment,\ 12\ °C}$	276 days	vP
Toxicity	NOEC	>35.59 µg/l	not T
PBT-statement:	The compound is not considered as PBT nor vPvB		

III.B Residues Documentation

Residue tests

No residue depletion studies were conducted because bioequivalence with the reference product was demonstrated. It was accepted that any minor differences in formulation to that of the reference product are not expected to impact on residue

depletion. In addition, decoquinate has low oral bioavailability and is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as 'No MRL required'.

Maximum Residue Limits

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

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provisions
Decoquinate	Not applicable	Bovine, ovine	No MRL required	Not applicable	For oral use only. Not for use in animals from which milk is produced for human consumption.

Withdrawal Periods

Based on the data provided, the following withdrawal periods are justified:
Cattle (calves) and sheep (lambs):
Meat and offal: zero days.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

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

***Development of resistance* and related risks in animals**

As this is a generic application, and the product is administered to the same target species for the same indications at the same posology using the same route of administration, the potential for resistance development is expected to be equivalent to that of the reference product.

Adequate warnings and precautions appear on the product literature.

Tolerance in the Target Species of Animals

No target animal tolerance studies in the target species were conducted.

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

IV.B Clinical trials

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

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 in the Union Product Database (UPD)

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.