MINISTERIO
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agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ketopain 300 mg/ml solution for use in drinking water for calves and pigs

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0300/001/DC
Name, strength and pharmaceutical form	Ketopain 300 mg/ml solution for use in drinking water for calves and pigs
Applicant	LABORATORIOS KARIZOO, S.A MAS PUJADES, 11-12, POL. IND. LA BORDA 08140. CALDES DE MONTBUI (Barcelona) - España
Active substance(s)	KETOPROFEN
ATC Vet code	QM01AE03 - Ketoprofen
Target species	PIGS AND CALVES
Indication for use	Treatment for the reduction of pyrexia and dyspnoea associated with respiratory disease in combination with anti-infective therapy, as appropriate.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralized procedure	D210: 13/03/2019.
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	CY,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 300 mg/ml of ketoprofen as active substance and the excipients arginine, citric acid and purified water.

The container/closure system is bottles made of white high density polyethylene with high density polyethylene screw cap, and include a 30 ml graduated cup for precise dose adjustment.

The particulars of the containers and controls performed are provided and conform to the regulation.

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 from 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 ketoprofen, 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.

Data relating to the active substance is presented in the form of a Ph. Eur. Certificate of Suitability (CEP).

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 site have been provided demonstrating compliance with the specification.

F. Stability

The Certificate of Suitability (CEP) of the active substance from the proposed source specifies the re-test period and storage 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 3 months after first opening the immediate packaging is supported by the data provided.

G. Other Information

The shelf life after dilution according to directions of 24 hours is supported by the data provided.

III. SAFETY AND RESIDUES ASSESSMENT

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

User Safety

The user safety aspects of this product are identical to 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

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. It can be concluded that the product does not pose a risk for the environment when used according to the SPC.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because this application is in accordance with Article 13 (1) – Generic application of Directive 2001/82/CE and bioequivalence with a reference product has been demonstrated.

MRLs

The active substance ketoprofen is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

MRLs are listed below:

Pharmacologically active substance	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Ketoprofen	Not aplicable	Bovine, porcine, Equidae	No MRL required	Not aplicable	No entry

Withdrawal Periods

The proposed meat and offal withdrawal period for the KETOPAIN 300 mg/ml is one day, the same as for the reference product. This is considered to be acceptable and in line with the current bioequivalence and withdrawal period calculation guidelines.

IV. CLINICAL ASSESSMENT (EFFICACY)

For generics, insert in the relevant sections as appropriate:

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

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 veterinary Heads of Agencies website (www.hma.eu).

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.

None