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

KETINK 300 mg/ml concentrate for oral solution for calves and pigs for fattening

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0241/001/DC
Name, strength and pharmaceutical form	Ketink 300 mg/ml concentrate for oral solution for calves and pigs for fattening
Applicant	ANIMEDICA ESPAÑA, S.L.U. Esmeralda, 19 E - 08950 (Esplugues de Llobregat) España
Active substance(s)	Ketoprofen
ATC Vet code	QM01AE03
Target species	Cattle (calf) and pig (pig for fattening)
Indication for use	Treatment for the reduction of pyrexia and dyspnoea associated with respiratory disease in combination with appropriate anti-infective therapy.

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MODULE 2

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

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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 decentralised procedure	24/02/2016
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, BG, CY, DE, EL, HU, IT, NL, PL, PT, RO, SI

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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. Composition

The product contains ketoprofen as active substance and sodium hydroxide, glycine, propylene glycol, citric acid monohydrate, and purified as excipients.

The container/closure system is bottle of 500 ml of high density polyethylene bottles (HDPE) heat-

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sealed with a polyethylene foil (PE) and a screw cap of HDPE equipped with a security system to give an airtight sealing. The particulars of the containers and controls performed are provided and conform to the regulation.

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.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is ketoprofen, an established active substance described in the European Veterinary 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.

Active substance has been controlled by Certificates of Suitability No. R1-CEP 2003-136-Rev 04 and No. R1-CEP 2007-167-Rev 00.

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

Scientific data have been provided and 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.

F. 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.

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G. 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.

The claim of a 3 months stability after broaching is based on the demonstration of stability for a batch broached and stored 3 months at 25 °C±2 / 60%±5%.

The in-use shelf-life of the reconstituted product of 24 hours is supported by the data provided.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL) (*for pharmaceuticals only)*

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, results of pharmacological or toxicological tests are not required.

Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

III.A Safety Testing

Pharmacological Studies

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

Toxicological Studies

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

User Safety

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The applicant has provided a complete user safety assessment in compliance with the relevant guideline (EMA/CVMP/543/03-Rev 1). This assessment shows that the different composition in the excipients compared to the reference product does not provide an additional risk for the user.

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline (CVMP/VICH/592/98-Final) which showed that no further assessment is required given that the PEC_{soil} values for all the target species (cattle and pigs) are below the action limit of 100 µg/kg.

Warnings and 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

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, no residue depletion studies are required.

MRLs

Ketoprofen is listed in Annex I of Commission Regulation Nº 37/2010, with a no MRL required status.

Withdrawal Periods

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the same withdrawal period of one day for meat and offal in cattle (calf) and pigs for fattening is justified.

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IV. CLINICAL ASSESSMENT (EFFICACY)

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.

IV.A Pre-Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, preclinical studies are not required.

IV.B Clinical Studies

As this was a generic application according to Article 13(1) of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, clinical studies are not required.

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.

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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).

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