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

KETOPROCEN 100 mg/ml SOLUTION FOR INJECTION

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0267/001/DC
Name, strength and pharmaceutical form	**KETOPROCEN 100 mg/ml SOLUTION FOR INJECTION**
Applicant	CENAVISA S.L. Camí Pedra Estela s/n 43205 Reus (SPAIN) Tel. 34 977 757 273 / Fax. 34 977 751 398 www.cenavisa.com / e-mail: cenavisa@cenavisa.com
Active substance(s)	Ketoprofen
ATC Vet code	QM01AE03
Target species	Horses, bovine and porcine.
Indication for use	In horses: treatment of inflammatory and painful states of the osteoarticular and musculoskeletal systems of sport and race horses, in particular: limps of traumatic origin, arthritis, arthrosis, articular injuries (sprains, synovitis), fractures, tendonitis, peritendinitis, hoof complaints (navicular disease, shoe accidents, pododermatitis circumscripta, founder), post-surgical inflammations. Symptomatic treatment of colic. In bovine: anti-inflammatory, analgesic and anti-pyretic treatment in: Musculoskeletal inflammatory processes. Mastitis. Mammary oedema. Inflammatory processes associated to respiratory diseases. Colic. In porcine: treatment of hyperthermia in acute diseases. In sows: treatment of Mastitis-Metritis-Agalactia syndrome.

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 Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	27/09/2016
Concerned Member States for original procedure	BG, HU, LT, LV, RO

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 Ketoprocen and Benzyl alcohol (E1519), arginine, citric acid monohydrate (E330) and water for injections

The container/closure system are 50 ml, 100 ml and 250 ml amber glass type II vials, with bromobutyl stopper and aluminium cap with FLIP-OFF seal. 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.

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 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.

State reference to the CEP is: R1-CEP 2003-136-Rev 04

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

Scientific data and/or certificates of suitability issued by the EDQM 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 site<s> have been provided demonstrating compliance with the specification.

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.

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13.1 of the Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, results of safety and residue tests are not required.

The safety and residue aspects of this product are identical to the reference product.

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 / 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

The applicant has not provided a user risk assessment. Ketoprocen 100 mg/ml solution for injection will be used in the same species, at the same doses and treatment regimen, and has the same qualitative and quantitative composition as the reference product. For these reasons, the risk for the user can be considered identical for both products.

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 which showed that no further assessment is required. The assessment concluded that the ERA can stop in question 5 of Phase I, since the product will be used only for treatment of a small number of animals.

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 for bovine, porcine and equidae.

Withdrawal Periods

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the same withdrawal periods are justified. In addition, withdrawal periods of 4 days in meat and zero hours is milk have been established horses, based on the extrapolation from cattle in accordance to guideline on safety and residue data requierements for veterinary medicinal products intended for minor uses or minor species (EMEA/CVMP/SWP/66781/2005). The following withdrawal periods are set for the product:

Horses: Meat: 4 days.
Milk: zero hours

Cattle: Meat: 4 days
Milk: zero hours

Pigs: Meat: 4 days.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13.1 of the Directive 2001/82/EC as amended, 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>

or

Complete this section for extensions to the same VPA range or defined, significant variations, using the table shown below.

Some examples of significant changes in safety or efficacy data are:

- *Changes to pharmacokinetic data leading to a change in the SPC*
- *Changes to toxicological data leading to a change in the SPC*
- *Changes to user safety warnings*
- *Changes to ecotoxicological information as given in the SPC or changes to disposal warnings*
- *New residue studies in new target species or tissues*
- *Reassessment of residue data or new studies resulting from changes to MRL*
- *Changes to withdrawal period*
- *Changes to target species*
- *Changes to target species tolerance data leading to change in warnings/precautions for target species*
- *New or changed indications*

Significant changes in administrative or quality data include any Type II change, which affects the initial report. The following Type IA or IB changes may also apply:

- *Name of product [Type IA: 2]*
- *Name of active substance [Type IA: 3}*
- *MAH [Type IA: 1]*
- *Composition of the medicinal product [Type IB: 18, Type IA/B: 25, 34, 35, 39]*
- *Container/closure system [Type 1/B: 26, 28, 29, 36, 41, 43]*
- *Method of preparation [Type 1B: 33]*
- *Active substance specification [Type IB: 25]*
- *CEP [Type IA/B: 15]*
- *Re-test period or storage conditions of active substance [Type IB: 17]*
- *Excipient specifications [Type 1A/B: 25]*
- *Packaging materials[Type 1A/B: 28, 29, 36, 41, 43]*
- *TSE [Type 1A: 16, 22]*
- *Shelf-life or storage conditions of the finished product [Type 1B: 42]*

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F-DMV-25-02

Quality changes

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**
<Example: Change to active substance specification> (MS/V/XXX/X/IB/XX)	N/A	

Safety/efficacy changes

Summary of change **(Type; application number)**	**Section updated in Module 3**	**Approval date**
<Example: Addition of target species - pigs> (MS/V/XXX/X/II/XX)	<IIIA> <IIIB> <IV>	