College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

KETOSAN, 100 mg/ml solution for injection for cattle and pigs

Date created: August 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0240/001/DC
Name, strength and pharmaceutical form	KETOSAN, 100 mg/ml solution for injection for cattle and pigs
Applicant	Interchemie werken “De Adelaar” B.V. Metaalweg 8 5804 CG Venray The Netherlands
Active substance(s)	Ketoprofen
ATC Vetcode	QM01AE03 (Nonsteroidal anti-inflammatory/ antirheumatic drugs (NSAIDs)
Target species	Cattle and pigs
Indication for use	Cattle: The product is indicated for the symptomatic treatment of fever in respiratory infections, as well as analgesic and anti-inflammatory treatment in musculoskeletal ailments and conditions of the udder. In calves, Ketosol-100 can be used to alleviate post-operative pain after dehorning or castration. Pig: The product is indicated for antipyretic and antiinflammatory treatment in diseases of the respiratory system and the mastitis-metritisagalactia (MMA) syndrome.

MODULE 2

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	4 July 2018
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BE, DE, UK

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.

Ketosan is a generic product in accordance with Article 13(1). The reference product is Ketofen 10% oplossing voor injectie voor runderen en varkens with marketing authorisation number REG NL 8784. The initial application for Ketofen 10% oplossing voor injectie voor runderen en varkens was assessed before there was a requirement to have a public assessment report.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains ketoprofen 100 mg/ml and the excipients benzyl alcohol, arginine, citric acid anhydrous and water for injections.

The container system consists of amber Type II glass 100 ml vials closed with a bromobutyl rubber stopper and aluminium cap

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

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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 ketoprofen, an established 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.

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 have 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 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at +25°C.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

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III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

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

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users, consumers and the environment.

III.A Safety Testing

User Safety

Being a generic procedure the applicant refers to the reference product for information on this section. Additionally the applicant has provided a user safety risk assessment in compliance with the relevant guideline. 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.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

III.B Residues documentation

Residue Studies

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

Withdrawal Periods

Based on the above the following withdrawal periods are justified:

Cattle:	Meat and offal:	4 days
	Milk:	zero hours
Pig:	Meat and offal:	5 days

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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.

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 Heads of Vetrinary Medicines 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.

Summary of change (Application number	**Section updated in Module 3**	**Approval date**
Changes to an existing pharmacovigilance system: Update of the DDPS (NL/V/0240/IA/001/G)	N/A	28 November 2018