MINISTERIO DE SANIDAD
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

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0388/001/DC
Name, strength and pharmaceutical form	Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Applicant	Labiana Life Sciences, S.A. c/Venus, 26 08228 Terrassa (Barcelona) Spain
Active substance(s)	Ketoprofen
ATC vet code	QM01AE03
Target species	Cattle, pigs and horses
Indication for use	Cattle: - Reduction of inflammation and pain associated with post-partum, musculoskeletal disorders and lameness. - Reduction of fever associated with bovine respiratory disease in combination with antimicrobial therapy where appropriate. - Reduction of inflammation, fever and pain in acute clinical mastitis in combination with antimicrobial therapy where appropriate. Pigs: - Reduction of pyrexia in cases of respiratory disease and Postpartum Dysglactia SyndromePDS- (Metritis Mastitis Agalactia syndrome) in sows, in combination with antimicrobial therapy, where appropriate. Horses: - Reduction of inflammation and pain associated with osteoarticular and musculoskeletal disorders (lameness, laminitis, osteoarthritis, synovitis, tendinitis, etc.). - Reduction of postoperative pain and inflammation. Reduction of visceral pain associated with colic.

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) Generic application of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	Day 210: 16/12/2020
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BG, EE, HR, HU, LT, LV, SI, UK.

I. SCIENTIFIC OVERVIEW

This was a generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended. *Labiprofen 150 mg/ml* is the generic veterinary medicinal product and contains ketoprofen as active substance for Intramuscular or Intravenous use. The reference product is *Dinalgen 150 mg/ml solución inyectable para bovino porcino y caballos* authorized in Spain since 2010.

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 ketoprofen and benzyl alcohol, arginine, citric acid monohydrate and water for injections as excipients.

The container/closure system is amber type II glass vials of 50 ml, 100 ml and 250 ml closed with bromobutyl stoppers and aluminium caps.

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.

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.

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

A re-test period of 5 years is specified on the Ph. Eur. CEP if the material is stored in a double polyethylene bag, placed in a cardboard drum.

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.

Appropriate data have been provided to support the in-use shelf-life of the product.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

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

The pharmacological aspects of this product are identical to the reference product.

Toxicological Studies

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

The toxicological aspects of this product are identical to the reference product.

User Safety

Although this is a generic application according to Article 13 and bioequivalence with the reference product has been demonstrated, the applicant has provided a brief user safety assessment broadly in accordance 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.

The environmental risk assessment can stop in Phase I, and no Phase II assessment is required because the veterinary medicinal product is intended to be used in cattle, pigs and horses through individual treatment to treat a small number of animals in a flock or herd.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because bioequivalence to the reference product has been demonstrated and there are no differences in the composition of the candidate product when compared to the reference product.

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:

	Bovine, Porcine, Equidae
Muscle	No MRL required
Liver	
Kidney	
Fat / skin	
Milk	

Withdrawal Periods

Based on the data provided above:

A withdrawal period of 2 days for meat and offal in bovine and zero hours for milk are justified.
A withdrawal period of 1 day for meat and offal in horses is justified.
A withdrawal period of 3 days for meat and offal in porcine is justified.

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 is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, pharmacodynamics, pharmacokinetics and tolerance 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