MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE MEDICAMENTOS VETERINARIOS

Agencia Española de Medicamentos y Productos Sanitarios

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28022 – Madrid
España
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

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PRODUCT SUMMARY

EU procedure number	ES/V/448/001/DC
Name, strength and pharmaceutical form	KETOPROCEN 150 mg/ml solution for injection for cattle, pigs and horses
Applicant	Calle Dels Boters 4 43205 Reus, Tarragona Spain
Active substance(s)	Ketoprofen
ATC vetcode	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. - 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 Dysgalactia Syndrome-PDS-(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.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP)	DINALGEN 150 mg/ml solution for injection for cattle, pigs and horses
Marketing authorisation holder	Ecuphar veterinaria S.L.U.
MS where the RP is or has been authorised	ES
Marketing authorisation number	2156 ESP
EU procedure number	ES/V/0115/001/DC
Date of authorisation	20/05/2010
Date of completion of the original decentralised procedure	Day 210: 01/10/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BG, DK, EE, HU, IE, LT, LV, PL, RO, SE
Withdrawn CMS during original decentralised procedure	None

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

2.A. Product description

The VMP contains 150 mg of ketoprofen per ml as active substance. Other ingredients are benzyl alcohol, arginine, citric acid, and water for injections.

The container/closure system consists of type II amber glass vials (100 ml and 250 ml) or amber polypropylene (PP) vials (100 ml and 250 ml), closed with type I bromobutyl stoppers and aluminium flip-off capsules.

The choice of the formulation and the presence of preservative are justified.

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

2.B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

2.C. Production and control of starting materials

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

Certificate of suitability issued by the EDQM has 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.

2.D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

2.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 VMP.

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.

2.F. Stability tests

A retest period and their storage conditions are declared at the Certificate of suitability issued by the EDQM.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

2.G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

3.A. Safety tests

Pharmacological studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of pharmacological tests are not required.

Toxicological studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that the candidate formulation will not present an unacceptable risk for the user than the reference product.

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

Environmental Risk Assessment

The application for marketing authorisation of KETOPROCEN 150 mg/ml solution for injection for cattle, pigs and horses is exempt from submitting an environmental risk assessment according to Article 18(7) of Regulation (EU) 2019/6, that indicates that an environmental safety data may be required when the reference product is authorized before October 2005. Since the reference product in this case was authorized in 2010, a full ERA is not required. No unacceptable risk for the environment is expected when the product is handled, used and disposed according to the information included in the product literature.

3.B. Residues documentation

Residue tests

No residue depletion studies were conducted because this is a generic application according to Article 18, and bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

Ketoprofen is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal Species**	**MRL**	**Target tissues**	**Other provision**	**Therapeutic Classification**
Ketoprofen	Ketoprofen	All ruminants, porcine, Equidae	50 µg/kg 20 µg/kg 20 µg/kg 50 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	For porcine species the fat MRL relates to 'skin and fat in natural proportions'	NO ENTRY
	Ketoprofen	Poultry	10 µg/kg 30 µg/kg 10 µg/kg 10 µg/kg	Muscle Skin and fat in natural proportion Liver Kidney	Not for use in animals from which eggs are produced for human consumption	NO ENTRY

Withdrawal Periods

The same withdrawal periods than the reference product are proposed:

Cattle:

Meat and offal: 2 days.
Milk: zero hours.

Horses:
Meat and offal: 1 day.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 3 days.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

4.A. Pre-Clinical Studies

Tolerance in the target species of animals

The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

4.B. Clinical trials

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

None.