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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail
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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Pyrocam 20 mg/mL solution for injection for cattle, pigs and horses
Vetcam 20 mg/mL solution for injection for cattle, pigs and horses

04 June 2024

PRODUCT SUMMARY

EU procedure number	FR/V/0471/001/DC
Name, strength and pharmaceutical form	Pyrocam 20 mg/ml solution for injection for cattle, pigs and horses (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, LU, MT, NL, PL, PT, RO, SK, UK (NI)) Vetcam 20 mg/ml solution for injection for cattle, pigs and horses (NO, SE, SI)
Applicant	HUVEPHARMA UITBREIDINGSTRAAT 80 ANTWERP 2600 BELGIUM
Active substance(s)	Meloxicam
ATC vetcode	QM01AC06
Target species	Cattle, pigs and horses
Indication for use	Cattle: For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle. For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle. For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy. For the relief of post-operative pain following dehorning in calves. Pigs: For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy. Horses: For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders. For the relief of pain associated with equine colic.

Pyrocam 20 mg/ml solution for injection for cattle, pigs and horses	FR/V/0471/001/DC
Huvepharma NV	DCP
Publicly available assessment report	

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 (EC) 2019/6 as amended.
Reference product (RP)	METACAM 20 mg/mL Solution for injection
Marketing authorisation holder	BOEHRINGER INGELHEIM VETMEDICA GMBH
Marketing authorisation number EU procedure number	EU/2/97/004/007-008-014-015-027-028-031-032 Centralised Procedure EMEA/V/C/000033
Date of authorisation	07/01/1998
Date of completion of the original decentralised procedure	08 May 2024
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, LU, MT, NL, NO, PL, PT, RO, SE, SI, SK, UK(NI)

*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)

A. Product description

The VMP contains 20 mg/mL of meloxicam as active substance and the excipients ethanol 96%, meglumine, macrogol 300, poloxamer 188, glycine, disodium edetate, sodium hydroxide, hydrochloric acid concentrated and water for injections.

The container/closure system is a glass vial closed with a bromobutyl rubber stopper.

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.

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.

C. Production and control of starting materials

The active substance is meloxicam, an established active 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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

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

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 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.

F. Stability tests

A re-test period is set in the Certificate of Suitability of the active substance.

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.

The in-use shelf life of the broached vials of VMP is supported by the data provided.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

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, pharmacological studies 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.

Other 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 other studies are not required.

User safety

The applicant has provided a user safety 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 VMP.

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 initial predicted environmental concentration in soil (PECsoil, initial = 3.5 µg/kg) is less than 100 µg/kg.

B. Residues documentation

Residue tests

The applicant has not submitted residue data on the basis that bioequivalence with the reference product has been justified.

Maximum Residue Limits

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

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
Meloxicam	Bovine, caprine, porcine, rabbit, Equidae	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/ Nonsteroidal anti-inflammatory agents	37/2010 in 22/12/2009
	Bovine, caprine	15 µg/kg	Milk			

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Cattle: Meat and offal: 15 days

Milk: 5 days

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

A. Pre-Clinical Studies

No pre-clinical studies were performed. The exemption of the need of in vivo bioequivalence studies to compare the rate and extent of absorption between the candidate and the reference veterinary medicinal products is acceptable according to the European “Guideline on the conduct of bioequivalence studies for veterinary medicinal products” (EMA/CVMP/EWP/16/2000-Rev.4, waivers from bioequivalence study requirements, 7.1).

Pharmacology

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

Dose determination and confirmation

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, dose determination and confirmation studies are not required. The reference is made to the originator dossier and the same dosage as per the reference product applies for the candidate product.

Tolerance in the target species of animals

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, tolerance studies are not required. The same adverse events (type and incidence) as observed with the reference product are mentioned in the product literature.

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 clinical studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

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.