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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

RHEUMOXIDYL 20 MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND HORSES

Date: 05/02/2026

PRODUCT SUMMARY

EU procedure number	FR/V/0448/001/DC - FR/V/0448/001/E/001
Name, strength and pharmaceutical form	RHEUMOXIDYL 20 MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND HORSES
Applicant	C & H GENERICS C/O MICHAEL MCEVOY & CO., SEVILLE HOUSE, NEW DOCK STREET GALWAY IRELAND
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. 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.

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 13.1 Generic Application (Directive No 2001/82/EC)
Date of completion of the original decentralised procedure	21/12/2022
Concerned Member States for original procedure	BE, DE, NL, IE
Withdrawn CMS	/

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 the active substance meloxicam (20mg/ml) and the excipients ethanol (96%), meglumine, macrogol 400, poloxamer 188, glycine, sodium hydroxide, hydrochloridric acid and water for injections.

The container/closure system is a clear glass vial (20 ml, 50 ml, 100 ml and 250 ml), closed with a type I bromobutyl rubber stopper.

The choice of the presence of preservative is 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 licensed manufacturing sites.

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 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

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 VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Toxicological studies

As this is a generic application according to Article 13.1(a)(iii) of Council Directive 2001/82/EC, as amended by Directive 2004/28/EC and bioequivalence with a reference VMP has been demonstrated, results of toxicological studies are not required.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that there is no unacceptable risk for the user.

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 VMP will be used to treat a small number of animals in a flock or herd.

B. Residues documentation

Residue tests

Residue depletion studies have been conducted in cattle and pigs. The measured meloxicam concentrations in the injection site (core and surrounding) were found to below the muscle MRL in samples from all animals in all groups at all sacrifice time points post treatment (days 4, 5 and 6 for pigs and 13, 15 and 17 for cattle). The MRL is not exceeded after 5 days.

The LC-MS/MS method for the determination of meloxicam in bovine and porcine tissues was fully validated.

Maximum Residue Limits

Meloxicam 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**
Meloxicam	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
		Bovine, caprine	15 µg/kg	Milk		

An acceptable daily intake (ADI) was defined for meloxicam. It is 1.25µg/kg bw (i.e. 87.5 µg/person)

Withdrawal Periods

Based on the data provided above, the withdrawal period of the reference product can be applied as follows:

Cattle:

Meat and offal: 15 days

Milk: 120 hours

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.

Pharmacology

The exemption of the need of *in vivo* bioequivalence study between the two products is acceptable according to the European “Guideline on the conduct of bioequivalence studies for veterinary medicinal products” (EMA/CVMP/016/00-Rev.2 - waiver from bioequivalence study requirements 7.1).

Tolerance in the target species of animals

As this is a generic application according to Article 13.1(a)(iii) of Council Directive 2001/82/EC, as amended by Directive 2004/28/EC and bioequivalence with a reference VMP has been demonstrated, results of tolerance studies are not required.

B. Clinical trials

As this is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended by Directive 2004/28/EC, 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.

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.