IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Carprodolor 50 mg/ml solution for injection for cattle

PRODUCT SUMMARY

EU Procedure number	IE/V/0620/001 (formerly UK/V/0429/001)
Name, strength and pharmaceutical form	Carprodolor 50 mg/ml solution for injection for cattle
Active substances(s)	Carprofen
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater Netherlands
Legal basis of application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Date of Authorisation	23 January 2013 (UK) 12 April 2013 (IE)
Target species	Cattle
Indication for use	The product is indicated as an adjunct to antimicrobial therapy to reduce clinical signs in acute infectious respiratory disease and acute mastitis in cattle.
ATCvet code	QM01AE91
Concerned Member States	Austria, Belgium, Czech Republic, Denmark, Estonia, Spain, Finland, France, Hungary, Iceland, Ireland (now RMS), Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Sweden

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.
The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is a solution for injection, developed as a generic of Rimadyl Cattle 50 mg/ml and bioequivalence with this product is claimed. Carprofen, the active substance, is a non-steroidal anti-inflammatory drug (NSAID) which can be used to control pain and inflammation in various disease conditions. Carprodolor 50 mg/ml Solution for Injection for Cattle is indicated in the treatment of acute respiratory infections and acute mastitis in cattle as an adjunct to antimicrobial therapy. The product is administered via a single subcutaneous or intravenous injection at a dosage of 1.4 mg/kg bodyweight.

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

II. QUALITY ASPECTS

A. Composition

The product contains 50 mg/ml carprofen as active substance and 96% ethanol, macrogol 400, poloxamer 188, ethanolamine and water for injections as excipients.

The container/closure system consists of 50 ml of solution packaged in Type I amber glass vials and closed with a red chlorobutyl rubber stopper with an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation. The choice of the formulation is justified.

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. The product is manufactured using conventional manufacturing techniques. The solution is prepared and filtered before the pre-sterilised vials are filled with 50 ml of the product, before a final sterilisation procedure is performed. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is carprofen, an established active substance not described in the European Pharmacopoeia (Ph. Eur). Data on the active substance was provided in the form of an Active Substance Master File (ASMF). The active substance is manufactured in accordance with the principles of good manufacturing practice (GMP).

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.

All excipients comply with their respective Ph. Eur monographs, except ethanolamine which meets the requirements of the British Pharmacopoeia monograph. Certificates of analysis were received from each manufacturer, and testing of the excipients is performed on receipt.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable.

F. 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. Tests on the finished product include those for identification of the active substance, identification of related impurities, pH and appearance.

G. 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. A retest period of 5 years was established for the active substance, the shelf-life of the product as packaged for sale is 2 years and the in-use shelf life is 28 days.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

- Shelf life of the product as packaged for sale: 3 years.
- Shelf life after first opening the immediate packaging: 28 days.
- Do not refrigerate or freeze.

- Keep the vial in the outer carton in order to protect from light.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, no basic pharmacology, pharmacokinetic or toxicology data is required for carprofen. Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

III.A Safety Testing

Pharmacological Studies

As this is a generic application submitted according to Article 13 (1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed because the nature of the product, results of pharmacological studies are not required.

Toxicological Studies

As this is a generic application submitted in according to Article 13 (1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed because of the nature of the product, results of toxicological studies are not required.

User Safety

As this is a generic application submitted in according to Article 13 (1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed because of the nature of the product, results of user safety tests are not required. The same warnings and precautions as the reference product are listed on the product literature and are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a limited first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that there will be minimal environmental exposure as the product is for limited numbers of animals.

III.B Residues documentation

Residue Studies

As this is a generic application submitted in according to Article 13 (1) of Directive 2001/82/EC as amended and bioequivalence with the reference product can be assumed because of the nature of the product, results of residues studies are not required.

Withdrawal Periods

A withdrawal period of 21 days for meat in cattle and zero hours for milk are justified.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Pharmacology

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

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, 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.B Clinical Studies

Laboratory Trials

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, 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 benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.