IPAR

(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Rycarfa 50 mg/ml solution for injection for dogs and cats.

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1 PRODUCT SUMMARY

MODULE1

EU Procedure number	IE/V/0317/001/DC
Name, strength and pharmaceutical form	Rycarfa 50 mg/ml solution for injection for dogs and cats
Applicant	KRKA, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia
Active substance(s)	Carprofen
ATC Vetcode	QM01AE91
Target species	Dogs and cats.
Indication for use	Dogs: For the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intraocular) surgery. Cats: For the control of post-operative pain following surgery.

MODULE2

The Summary of Product Characteristics (SPC) for this product is available on the veterinary Heads of Agencies website (www.hma.eu).

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2 PUBLIC ASSESSMENT REPORT

Legal basis of original application	Article 13(1) of Directive 2001/82/EC, as amended.
Date of completion of the original decentralised procedure	19th December 2013.
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	Austria, Belgium, Germany, Denmark, Greece, Spain, Finland, France, Italy, Netherlands, Norway, Portugal, Sweden, United Kingdom.

2.1 I Scientific Overview

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; possible adverse reactions are clearly indicated in the SPC.

The product is safe for the user 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 by way of reference to an already authorised veterinary medicinal product (Rimadyl Injection; Pfizer Healthcare Ireland).

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

2.2 II Quality Aspects

A. Composition

The product contains 50 mg/ml of carprofen and the excipients arginine, glycocholic acid, lecithin, benzyl alcohol, sodium hydroxide, hydrochloric acid and water for injections.

The container/closure system is 20 ml Type I amber glass vials with bromobutyl rubber stoppers and aluminium seals. The particulars of the containers and controls performed are provided and conform to the regulation.

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 carprofen, 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.

Data relating to the active substance is presented in the form of an Active Substance Master File (ASMF).

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

Scientific data 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.

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 site have been provided demonstrating compliance with the specification.

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.

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.

H. Genetically Modified Organisms

Not applicable.

J. Other

Information None.

2.3 III Safety and residues assessment (pharmaco-toxicological)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety and residue tests or of pre-clinical and clinical trials are not required.

The safety aspects of this product are considered to be the same as those of the reference product.

Warnings and precautions as listed on the product literature are in line with those of the reference product and other similar products recently authorised and are considered adequate to ensure safety of the product to users and the environment.

III.A Safety Testing Pharmacological Studies Toxicological Studies Other Studies Observations in Humans

This application is submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended (a generic application). Given that the applicant has satisfactorily justified an exemption from the requirement to demonstrate *in-vivo* bioequivalence with the reference product, the provision of the results of safety and residue tests is not required.

User Safety

The applicant has provided a user safety assessment.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product and are in line with those of the reference product and other similar products recently authorised. The warnings and precautions are considered adequate to ensure safety of the product to users.

Ecotoxicity

Phase I

An environmental risk assessment (ERA) was provided. The environmental risk assessment can stop in Phase I because the assessment showed that the product will only be used in non-food animals.

Conclusion

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

Not applicable as only for use in non-food producing animals.

2.4 IV Clinical Assessment

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 and other similar products recently authorised.

IV.A Pre-Clinical Studies

Pharmacology

No data were required as it could be accepted that the test and reference products are sufficiently similar to be considered equivalent and that exemption from the requirement for *in-vivo* bioequivalence data is justified in accordance with relevant guidelines.

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Tolerance in the Target Species of Animals

Tolerance data specific to the candidate formulation were not required as it could be accepted that the test and reference products are sufficiently similar to be considered equivalent and that target animal tolerance is not expected to differ for the candidate forumulation when compared with the reference product.

Resistance

Given the nature of the active substance (a non-steroidal anti-inflammatory drug), the omission or data on the development of resistance is appropriate.

IV.B Clinical Studies

Laboratory Trials Field Trials

This application is submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended (a generic application). Given that the applicant has satisfactorily justified an exemption from the requirement to demonstrate *in-vivo* bioequivalence with the reference product, the provision of the results of clinical trials is not required.

The product is to be administered by the same routes of administration, to the same target species using the same dose rate and frequency as that approved for the reference product. Therefore, the product is expected to be as effective as the reference product when used in accordance with the proposed SPC.

2.5 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.