IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Rycarfa 100 mg tablets for dogs

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PRODUCT SUMMARY

EU Procedure number	IE/V/0316/003/DC
Name, strength and pharmaceutical form	Rycarfa 100 mg tablets for dogs.
Active substance	Carprofen
Marketing Authorisation Holder	Krka d.d. Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia
Legal basis of application	Generic applications in accordance with Article 13.1 of Directive 2001/82/EC, as amended.
Date of completion of procedure	23October 2013
Target species	Dogs.
Indication for use	Reduction of inflammation and pain caused by musculoskeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain
ATCvet code	QM01AE91
Concerned Member States	AT, BE, DE, DK, EL, ES, FI, FR, IT, NL, NO, PT, SE, UK

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 authorisations for the specific veterinary medicinal products. 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 products for marketing in Ireland.

The Summary of Product Characteristics (SPC) for these products are available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The products are produced and controlled using validated methods and tests, which ensure the consistency of the products released on the market.

It has been shown that the products can be safely used in the target species. Possible adverse reactions are indicated in the SPC.

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The products are safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The safety and efficacy of the products were demonstrated by demonstrating bioequivalence to a reference product in order to support the claims made in the SPC.

The overall benefit/risk analysis is in favour of granting the marketing authorisations.

II. QUALITY ASPECTS

A .Qualitative and Quantitative Particulars

The products contain 20 mg, 50 mg or 100 mg respectively of carprofen and excipients lactose monohydrate, maize starch, ferric oxide red, ferric oxide black, povidone K30, sodium starch glycolate, colloidal anhydrous silica, meat flavour 10022, talc and magnesium stearate.
The container/closure system consists of laminated OPA/AL/PVC foil and Aluminium foil with pack sizes of 20, 50, 100 or 500 tablets.
The products are an established pharmaceutical form and their development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The products are manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.
Process validation data on the products have been presented in accordance with the relevant European guidelines

C. Control of Starting Materials

The active substance is Carprofen, an established 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.

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

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.

D. Control on Intermediate Products

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 specifications, and their limits, have been justified and are considered appropriate to adequately control the quality of the products.
Satisfactory validation data for the analytical methods have been provided.

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Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. 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 approvedconditions.
Stability data on the finished products has been provided in accordance with applicable European guidelines, demonstrating the stability of the products throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product (Rimadyl Compresse 100 mg; Pfizer) has been demonstrated, results of safety and efficacy tests are not required.

It can be accepted that the safety and efficacy aspects of this product are the same as 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 via European procedures. The warnings and precautions are considered adequate to ensure safety of the product to users and the environment.

III.A Safety Testing

Pharmacological Studies

The applicant conducted an *in-vivo* bioequivalence study comparing the pharmacokinetic profiles of Rycarfa 100 mg tablets with Rimadyl Compresse 100 mg tablets (see part IV.A of this assessment report).
Bioequivalence between candidate and reference products was accepted based upon the data presented.

Toxicological Studies
No toxicological data was required given that bioequivalence with the reference product was satisfactorily demonstrated.

User Safety

The applicant has provided a user safety assessment in line with the relevant guideline. The concentration of the active substance (carprofen) is identical to that of the reference product. The user safety warnings and precautions as listed on the product literature are in line with those approved for the reference product and other similar products recently authorised via European procedures and are considered adequate to ensure safety to users of the product.

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Environmental Risk Assessment

Phase I

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that as the product will only be used in non-food animals, the assessment may stop in phase I.

Warnings and precautions as listed on the product literature are in line with those approved for the reference product and other similar products recently authorised via European procedures and are considered adequate to ensure safety to the environment when the product is used as directed.

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.

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 in line with those approved for the reference product and other similar products recently authorised via European procedures.

IV.A Pre-Clinical Studies

Pharmacology

The applicant has conducted an *in-vivo* bioequivalence study using the 100 mg tablet strength in order to demonstrate bioequivalence between the candidate formulation (Rycarfa 100 mg) and the reference product (Rimadyl Compresse 100 mg; Pfizer). The results of this study demonstrated that the 100 mg presentations of the test and reference products are bioequivalent for the pivotal pharmacokinetic parameters AUCt, AUC∞ and C_{max}.

Bioequivalence of the lower tablet strengths (20 mg and 50 mg) was satisfactorily demonstrated by means of *in-vitro*- dissolution studies.

Tolerance in the Target Species of Animals

No target animal tolerance was conducted using the candidate formulation. Given the identical concentrations of active substances between candidate and reference product formulations, the safety profile of the proposed excipients and absence of tolerance issues in the *in-vivo*bioequivalence study, the absence of a specific tolerance study was accepted.

Resistance

Given the nature of the active substance (a non-steroidal anti-inflammatory drug), data on resistance was not required.

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IV.B Clinical Studies

Laboratory Trials

As bioequivalence between the candidate formulation and the reference product was satisfactorily demonstrated for all three tablet strengths, no clinical data was required.

Field Trials

As bioequivalence between the candidate formulation and the reference product was satisfactorily demonstrated for all three tablet strengths, no field study data was required.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrates 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.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

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 product.

Changes:
None.

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