IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Carprox vet 20 mg tablets for dogs

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PRODUCT SUMMARY

EU Procedure number	IE/V/0239/002/DC
Name, strength and pharmaceutical form	Rycarfa 20mg Tablets for Dogs
Active substance	Carprofen
Marketing Authorisation Holder	Krka dd Novo Mesto Smarjeska cesta 6 8501 Novo mesto Slovenia
Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of procedure	28th April 2010
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	CZ, DE, EE, ES, FR, HU, IT, LT, LV, NL, PL, RO, SI, SK, 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 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 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 known reactions typically observed for this class of active substance (NSAID) are 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 by the demonstration of bioequivalence with the reference product and the claims made in the SPC are in line with those included in the SPC of the reference product. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

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II QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 20 mg Carprofen and the 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 a blister pack comprised of laminated OPA/AL/PVC foil and Aluminium foil with pack sizes of 20, 50, 100 or 500 tablets.

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 at 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.

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 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.

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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 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.

G. Other Information

Not applicable.

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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, results of safety, pre-clinical and clinical trials are not required.

It can be concluded that the safety and efficacy aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are in line with those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Testing

Pharmacological Studies

No data provided.

This application is submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended (a generic application). As such, where bioequivalence with the reference product has been demonstrated, the omission of the results of safety and residue tests or of pre-clinical and clinical trials may be accepted.

In support of this application, the Applicant conducted a single *in vivo* study for the purposes of demonstrating that the test product Rycarfa 20 mg tablets for dogs) and the pioneer product (Rimadyl Tablets) are bioequivalent. The bioequivalence study was conducted using the 100 mg tablet (The reference product used in the bioequivalence study was Rimadyl Compresse 100 mg (Pfizer Italia)). In addition to the *in vivo* bioequivalence study, the Applicant provided *in vitro* dissolution data to support the bioequivalence of the other dosage strengths (20 mg and 50 mg).

Toxicological Studies

No data provided.

This application is submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended (a generic application). As such, where bioequivalence with the reference product has been demonstrated, the omission of the results of safety and residue tests or of pre-clinical and clinical trials may be accepted. ***Other Studies***

No data provided.

This application is submitted in accordance with Article 13.1 of Directive 2001/82/EC, as amended (a generic application). As such, where bioequivalence with the reference product has been demonstrated, the omission of the results of safety and residue tests or of pre-clinical and clinical trials may be accepted.

With respect to the excipients used in this formulation, all are well known and are commonly used in both human and/or veterinary medicinal products. The excipients are pharmacopoeial quality where relevant, chosen to produce a mixture with satisfactory flow and compression, and which would give appropriate and consistent dissolution results. A flavourant was added to the formulation, though no specific palatability is claimed. The justification for the use of the excipients is satisfactory and their inclusion is acceptable.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that when used in accordance with label recommendations, the product does not pose a risk to users.

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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 included in the product literature of other similar carprofen containing products recently authorised through European procedures.

Environmental Risk Assessment

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 The ERA provided by the applicant indicates that the assessment can be stopped at Phase I on the basis that the product is to be administered only to nonfood producing animals.

Furthermore, the applicant proposed that the same disposal advice as appears in the SPC of the reference product be included in the SPC; namely:

'Any unused product or waste material should be disposed of in accordance with national requirements'.

No specific warnings regarding the environment are therefore required.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13.1 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.

In support of this application, the Applicant conducted a single *in vivo* cross-over bioavailability study for the purposes of demonstrating that the test product (Rycarfa 20 mg tablets for dogs) and the pioneer product (Rimadyl Tablets) are bioequivalent. The bioequivalence study was conducted using the 100 mg tablet (The reference product used in the bioequivalence study was Rimadyl Compresse 100 mg (Pfizer Italia)). In addition to the *in vivo* bioequivalence study, the Applicant provided *in vitro* dissolution data to support the bioequivalence of the other dosage strengths (20 mg and 50 mg).

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

A target animal safety study specific to the test product has not been presented with the application. Based on the fact that bioequivalence to the reference product is claimed, it is accepted that a difference in tolerance profile relating to the carprofen component would not be expected. The proposed indications and posology for the test product are identical/similar to the authorised indications and posology of the reference product.

With respect to the excipients, all are widely used in the veterinary pharmaceutical industry and/or are generally recognised as safe, such that they are not expected to present any toxicological hazard to the target animal at the inclusion levels in this product.

The product literature accurately reflects the type and incidence of adverse effects which might be expected for this class of active substance (NSAID).

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IV.B Clinical Studies

As this is a generic application according to Article 13.1 and bioequivalence with a reference product has been demonstrated, the results of clinical 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.

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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