IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Carprofen KRKA 50 mg/ml solution for injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Carprofen KRKA 50 mg/ml solution for injection for dogs and cats
Active substance	Carprofen
Marketing Authorisation Holder	KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Legal basis of application	Generic application submitted in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of	
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.
ATCvet code	QM01AE91

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 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 slight reactions to be expected following the use of this 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 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. Qualitative and Quantitative Particulars

The product contains 50 mg/ml carprofen and the excipients arginine, glycocholic acid, lecithin, benzyl alcohol, sodium hydroxide, dilute hydrochloric acid and water for injections.
The container/closure system is a 20 ml amber glass vial closed with a rubber stopper and an aluminium seal.

The choice of the preservative 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 at a licensed manufacturing site.

Process validation data for the manufacturing process has 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 has been provided.

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

Scientific data and/or certificates of suitability issued by the EDQM 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.

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 has been provided.
Batch analytical data from the proposed production sites has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has 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 has 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.

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 the same 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

The application is submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application). Exemption from bioequivalence studies is claimed. This is accepted on the basis that the product is to be parenterally administered as a solution and contains the same active substance and excipients in the same concentrations as a veterinary medicinal product currently approved for use in the target species (Rimadyl Injection).

Based on the data presented it can 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.

Toxicological Studies

Given the type of application (generic) no toxicological data was required.

Observations in Humans

Given the type of application (generic) no toxicological data was required.

User Safety

The applicant has provided a user safety statement which shows that the hazard and risk posed by the product will be identical to that of the reference product, Rimadyl Injection.
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 non-food 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'.

The assessment concluded that no product-specific warnings in respect of the environment are 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 and reflect those approved for the reference product.

III.B Residues Documentation

Not applicable.

IV CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1) and an exemption from the requirement to demonstrate bioequivalence with the reference product has been adequately supported, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology

No data required.

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 data presented it can be accepted that the test and reference products are sufficiently similar to be considered equivalent and therefore target animal tolerance studies are not required.

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.

IV.B Clinical Studies

Based on the data presented it can be accepted that the test and reference products are sufficiently similar to be considered equivalent and therefore 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.