IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Cephacare flavour 500 mg tablets for dogs

PRODUCT SUMMARY

EU Procedure Number	IE/V/0454/003 (formerly UK/V/0251/003)
Name, Strength, Pharmaceutical Form	Cephacare flavour 500 mg tablets for dogs
Active Substances(s)	Cefalexin as cefalexin monohydrate
Applicant	Ecuphar NV Legeweg 157-I 8020 Oostkamp Belgium
Legal Basis of Application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Target Species	Dogs
Indication For Use	Treatment of infections of the respiratory tract, gastro-intestinal tract, urogenital tract, the skin and localised infections in soft tissue caused by bacteria sensitive to cefalexin.
ATC Code	QJ01DB01
Date of completion of the original decentralised procedure	01 October 2008 (UK) 19 December 2008 (IE)
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	Austria Belgium France Germany Ireland (now RMS) Luxembourg Portugal Spain UK added via RMS change

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 beige, round biconvex tablet for oral administration in dogs. It contains 500 mg Cefalexin as cefalexin monohydrate. Cefalexin has a broad spectrum activity against a wide range of bacteria. The recommended dose rate is 15 mg/kg bodyweight twice daily for 5 days.

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

This is a generic application based on bioequivalence to Ceporex Vet 50, 50 mg tablets and Ceporex Vet 250, 250 mg tablets. These products were first authorised in the UK on 16th July 1991. Additional data have been provided to support the 500 mg tablet strength.

II. QUALITY ASPECTS

A. Composition

The product contains 500 mg of the active substance Cefalexin as Cefalexin Monohydrate and the excipients Lactose Monohydrate, Potato Starch, Magnesium Stearate and Beef Flavour.

The container/closure system comprises a heat sealed PVC/aluminium foil blister containing 10 tablets. Either 10 or 25 blister strips are then packed into a cardboard carton. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and absence of preservative are 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.

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 Cefalexin, 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.

The active substance is supplied in accordance with a European Pharmacopoeia Certificate of Suitability.

Excipients, apart from the Beef Flavour, are the subject of monographs in the European Pharmacopoeia. Compliance with the requirements of the pharmacopoeia was therefore applied as the specification for each of these ingredients. The Beef Flavour, complies fully with Directive 88/388/EC concerning labelling of foods flavours and meets an in-house specification.

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

There are no intermediate products.

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.

G. Stability

Stability data on Cefalexin 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
Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Return any ½ tablet to the blister pack and use within 24 hours

Special precautions for storage
Do not store above 25ºC
Store in a dry place
Keep the blister in the outer carton

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing
Pharmacological Studies
As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of this product are identical to the reference products.

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 and the environment.

Toxicological Studies
As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

The toxicological aspects of this product are identical to the reference products.

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 and the environment.

User Safety
The applicant has not submitted a user risk assessment for the proposed products which has been justified on the basis of the applications being for generic products and that the use is considered identical to that of the reference products. The user warnings proposed are the same as the reference products as given below:

> Penicillins and cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross-reactions to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
> Do not handle this product if you know you are sensitised to or if you have been advised not to be in contact with such substances.
> Handle this product with great care to avoid exposure, taking all recommended precautions.
> If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
> In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
> Wash hands after use.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was not 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

IV.A Pre-Clinical Studies

Pharmacology

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 products.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, tolerance studies are not required. The safety claims for this product are equivalent to those of the reference products.

Resistance

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, resistance data are not required.

IV.B Clinical Studies

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 products.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.