Veterinary Medicines Directorate

**United Kingdom**
**Veterinary Medicines Directorate**
**Woodham Lane**
**New Haw**
**Addlestone**
**Surrey KT15 3LS**

**NATIONAL PROCEDURE**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

**Petalexin 75 mg Tablets for Dogs and Cats**
**Petalexin 300 mg Tablets for Dogs**
**Petalexin 600 mg Tablets for Dogs**

**Date Created: Jan 2018**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | Petalexin 75 mg Tablets for Dogs and Cats<br>Petalexin 300 mg Tablets for Dogs<br>Petalexin 600 mg Tablets for Dogs |
| Applicant | Alfamed<br>13ème rue - L.I.D<br>Carros Cedex<br>06517<br>France |
| Active substance | Cefalexin |
| ATC Vetcode | QJ01DB01 |
| Target species | Dogs and Cats, Dogs |
| Indication for use | <u>Petalexin 75 mg Tablets for Dogs and Cats</u><br><br>For the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to Cefalexin.<br>For the treatment of cutaneous and subcutaneous infections (wounds and abscesses) in cats caused by organisms susceptible to Cefalexin.<br>For the treatment of urinary-tract infections in cats and dogs (including nephritis and cystitis) caused by organisms susceptible to Cefalexin.<br><br><u>Petalexin 300 mg Tablets for Dogs</u><br><u>Petalexin 600 mg Tablets for Dogs</u><br><br>For the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to Cefalexin. |

| | |
|---|---|
| | For the treatment of urinary-tract infections in dogs (including nephritis and cystitis) caused by organisms susceptible to Cefalexin. |

# MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

# MODULE 3

## PUBLIC ASSESSMENT REPORT

| | |
|---|---|
| Legal basis of original application | Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended. |
| Date of conclusion of the procedure | 15th January 2018 |

## I. SCIENTIFIC OVERVIEW

These were applications for generic products, submitted in accordance with Article 13 (1) of Directive 2001/82/EC, as amended. The reference products are Rilexine 75 mg Tablets for Dogs and Cats, Rilexine 300 mg Tablets for Dogs and Rilexine 600 mg Tablets for Dogs, first authorised in the UK in October 2005.

Petalexin 75 mg Tablets for Dogs and Cats

The product is indicated for the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to Cefalexin. It is also indicated for the treatment of cutaneous and subcutaneous infections (wounds and abscesses) in cats caused by organisms susceptible to Cefalexin. Additionally, the product is for the treatment of urinary-tract infections in cats and dogs (including nephritis and cystitis) caused by organisms susceptible to Cefalexin.

Petalexin 300 mg and 600 mg Tablet for Dogs

The products are indicated for the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to Cefalexin, and for the treatment of urinary-tract infections in dogs (including nephritis and cystitis) caused by organisms susceptible to Cefalexin.

The products are 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 products can be safely used in the target species, any reactions observed are indicated in the SPC.[1] 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 [2] of the products was demonstrated

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting marketing authorisations.

## II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTIUENTS

### *II.A. Composition*

The products contain 75 mg, 300 mg or 600 mg of cefalexin, and the excipients crospovidone, mannitol, starch pregelatinised, croscarmellose sodium, colloidal anhydrous silica, colloidal hydrated silica, povidone K30, microcrystalline cellulose type A, poultry liver powder, magnesium stearate and microcrystalline cellulose type B.

The container/closure system consists of blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil. The particulars of the containers and controls performed are provided and conform to the regulation. There are 30 blisters of 7 tablets, which may be divided in half.

The choice of the formulation and the 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.

### *II.B. Description of the Manufacturing Method*

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of a simple process of granulation and tabletting of the ingredients. Process validation data on the product have been presented in accordance with the relevant European guidelines.

### *II.C. Control of Starting Materials*

The active substance is cephalexin monohydrate, an established active substance described in the European Pharmacopoeia (Ph. Eur). 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. An acceptable certificate of suitability was provided.

All excipients apart from pharmburst B1 and poultry liver powder are monographed in the Ph. Eur. Packaging components for the products conforms to Ph. Eur monographs.

### *II.C.4. Substances of Biological Origin*

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

### *II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process*

Not applicable.

### *II.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. Control tests on the finished product include those for: appearance, size, uniformity of dosage forms, resistance to crushing, disintegration time, water content, friability, identification and assay of the active substance, microbiological quality, purity tests and pharmaceutical tests.

### *II.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. The retest period is 60 months when stored in low-density polyethylene bags (both strip sealed), placed in a fibre drum.

Stability data on the finished products showed that all parameters tested remained within specification.

## *G. Other Information*

Keep the blisters in the outer carton.
Divided tablets should be stored in blister packs.
Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil.

# III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

## *III.A Safety Documentation*

### *Pharmacological Studies*

No pharmacological or toxicological data were required, other than that submitted to support the user risk assessment (URA). An environmental risk assessment (ERA) was also submitted.

### *User Safety*

A user risk assessment was provided in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. The warnings are the same as those of the reference products, and include an item added with regard to use of the divisible tablets, which highlights the need to avoid prolonged skin contact. Therefore the following applicant's user recommendations are appropriate:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.

1- Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

2- Handle this product with great care to avoid exposure, taking all recommended precautions. Take care to avoid prolonged skin contact. Wash hands after use.

3- If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more-serious symptoms and require urgent medical attention.

### *Environmental Safety*

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

**Phase I:**
The product will only be used in non-food animals and as a result, environmental exposure will be low. A Phase II ERA was not required.

# IV. CLINICAL DOCUMENTATION

## *IV.I. Pre-Clinical Studies, (including tolerance in the target species and resistance)*

As the products were considered to be bioequivalent to the reference products, (same qualitative and quantitative composition for active and excipients, and the same physicochemical properties), the products are permitted authorisation for generic products under section 7.1.d of the CVMP guideline EMA/CVMP/016/00-Rev.2. Therefore not further data were required.

## *IV.II. Clinical Documentation*

As the products were considered to be bioequivalent to the reference products, (same qualitative and quantitative composition for active and excipients, and the same physicochemical properties), the products are permitted authorisation for generic products under section 7.1.d of the CVMP guideline EMA/CVMP/016/00-Rev.2. Therefore not further data were required.

# V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are used in accordance with the Summary of Product Characteristics the benefit/risk profile of the products is favourable.

# MODULE 4

## 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)