Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Audolyn Ear Drops and Cutaneous Suspension for Cats and Dogs
Chanear Ear Drops and Cutaneous Suspension for Cats and Dogs
Earolan Ear Drops and Cutaneous Suspension for Cats and Dogs
Otisur Ear Drops and Cutaneous Suspension for Cats and Dogs

Date Created: December 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Chanear Ear Drops and Cutaneous Suspension for Cats and Dogs
Applicant	EU Pharmaceuticals Ltd, 37 Geraldine Road, London, SW18 2NR
Active substance	Miconazole Nitrate Polymyxin B Sulphate Prednisolone Acetate
ATC Vetcode	QP54AA51
Target species	Cats Dogs
Indication for use	For the topical treatment of otitis externa and skin infections caused by Gram-positive bacteria e.g. *Staphylococcus aureus, Streptococcus* spp., and Gram-negative bacteria *Escherichia coli* and *Pseudomonas aeruginosa*. For the topical treatment of otitis externa and skin infections caused by fungi and yeasts: *Trichophyton* spp., *Microsporum* spp., *Malassezia pachydermatis, Candida* spp. For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis* and complicated by microorganisms sensitive to miconazole and polymyxin B. The product also has anti-inflammatory and anti-pruritic activity.

MODULE 2

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

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic hybrid application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10a) as amended.
Date of conclusion of the procedure	18/09/24

I. SCIENTIFIC OVERVIEW

These are 'hybrid' applications because the products are for topical use, and therefore bioequivalence cannot be established through bioavailability studies. The reference product for GB is Surolan Ear Drops and Cutaneous Suspension which has been authorised in the UK since 1985.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains miconazole nitrate, prednisolone acetate and polymyxin B sulphate and the excipients silica colloidal anhydrous and liquid paraffin.

The container/closure system consists of low-density polyethylene (LDPE) squeezy bottle sealed with high-density polyethylene (HDPE) screw-fit cap. The particulars of the containers and controls performed are provided and conform to the regulation.

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 regulatory 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 product is manufactured in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substances are miconazole nitrate, prednisolone acetate and polymyxin B sulphate are 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.

II.C.4. Substances of Biological Origin

Scientific data and 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.

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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those suitable for this pharmaceutical form.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable regulatory 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 regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months.
Do not store above 25 °C. Do not refrigerate. Keep the container in the outer carton in order to protect from light.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Miconazole nitrate is a synthetic imidazole derivative with a pronounced antifungal activity and a potent activity against Gram-positive bacteria. Miconazole selectively inhibits the synthesis of ergosterol, which is an essential component of the membrane of yeasts and fungi.

Polymyxin B sulphate is a polypeptide antibiotic with bactericidal activity against Gram-negative bacteria. It binds to phospholipids in the cytoplasmic membrane, whereby the membrane permeability is disturbed. This results in lysis of the bacteria.

Prednisolone acetate is a glucocorticoid with strong anti-inflammatory activity which results from its reduction of the permeability of capillaries and vascular proliferation and from the inhibition of fibroblast action.

After topical application of miconazole nitrate, virtually no systemic absorption takes place through the skin or mucus membranes.

Systemic absorption of prednisolone on normal or abraded skin is minimal. Absorption of Polymyxin B sulphate via the skin is also negligible. Excretion is almost completely via the kidneys.

Toxicological Studies

Not applicable due to the legal basis of the product.

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. Therefore the following applicant's user recommendations are appropriate:

- People with known hypersensitivity to prednisolone, polymyxin B or miconazole should avoid contact with the veterinary medicinal product.
- The product may cause irritation to skin and eyes.
- Corticosteroids may produce irreversible effects in the skin. They can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy.
- Avoid contact with skin or eyes. Always wear single use disposable gloves when applying the product to animals. In case of accidental contact, skin or eyes should be rinsed immediately with plenty of water.

- Wash hands after use.
- Accidental ingestion of the product by a child may cause gastro-intestinal disturbances. Do not leave the filled dropper unattended. In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

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

Tolerance in the Target Species

Tolerance studies were not required because bioequivalence was established.

IV.II. Clinical Documentation

Not required due to the legal basis of the application.

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 of the product(s) 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.

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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.

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