IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Chanear

PRODUCT SUMMARY

EU Procedure number	IE/V/0665/001/DC
Name, strength and pharmaceutical form	Chanear 23.0 mg/ml + 5.0 mg/ml + 5500 IU/ml ear drops, suspension
Active substance(s)	Miconazole nitrate Prednisolone acetate Polymyxin B sulfate
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Loughrea Co. Galway Ireland
Legal basis of application	Application in accordance with Article 13(3) of Directive 2001/82/EC, as amended.
Date of completion of procedure	19/10/2022
Target species	Cats and dogs
Indication for use	For the treatment of otitis externa and small, localised, superficial skin infections caused by mixed infections with the following miconazole and polymixin B susceptible bacteria and fungi: • Gram-positive bacteria: *Staphylococcus* spp. and *Streptococcus* spp. • Gram-negative bacteria: *Pseudomonas* spp. and *Escherichia coli* • Fungi: *Malassezia pachydermatis*, *Candida* spp., *Microsporum* spp. and *Trichophyton* spp. Treatment of *Otodectes cynotis* (ear mites) infestations where there is concurrent infection with bacteria and fungi susceptible to polymyxin B and miconazole.
ATCvet code	QS02CA01
Concerned Member States	BE, DE, EL, ES, FR, IT, NL, RO

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

This application was submitted using the decentralised procedure by Chanelle Pharmaceuticals Manufacturing Ltd in accordance with paragraph 3 of Article 13 of Directive 2001/82/EC (a "hybrid" veterinary medicinal product).
The reference product cited in this application is Surolan Ear Drops and Cutaneous Suspension (Elanco GmbH, marketing authorisation number VPA22020/032/001) which was first granted a marketing authorisation in the RMS on 1st October 1988. The reference product has been authorised within the Community for not less than 10 years based upon a full dossier.

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

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars
The product contains 23 mg/ml of the active substance miconizole nitrate, 5 mg/ml of the active substance prednisolone acetate and 5500 IU/ml of the active substance polymixin B sulfate and the excipients colloidal anhydrous silica and liquid paraffin. The container/closure system is 15 ml or 30 ml white low-density polyethylene squeeze dropper bottles with a white, high-density polyethylene screw-cap and a white, low-density polyethylene dropper. 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 substances are miconizole nitrate, prednisolone acetate and polymixin B sulfate, established active substances described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice. The active substance specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with the specifications 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 has been provided. Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability
Stability data on the active substances has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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 ASSESSMENT

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

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

User Safety

The user safety profile of the veterinary medicinal product is the same as that of the reference product. Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users.

- People with known hypersensitivity to prednisolone, polymyxin B or miconazole should avoid contact with the veterinary medicinal product.
- The veterinary medicinal product may cause irritation to skin and eyes. Avoid contact with skin or eyes. Always wear single use disposable gloves when applying the veterinary medicinal product to animals. In case of accidental spillage, skin or eyes should be rinsed immediately with plenty of water. Wash hands after use.
- Take care to avoid accidental ingestion. In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

Environmental Risk Assessment
Phase I
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the product is intended for use in non-food-producing animals (cats and dogs).
The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies
Tolerance in the Target Species of Animals
As this is a hybrid application according to Article 13, and bioequivalence with a reference product has been demonstrated, target animal tolerance studies are not required. The tolerance profile for this product is equivalent to that of the reference product.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance
The potential for resistance development does not differ from that of the reference product. Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies
As this is a hybrid 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 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.