Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ototop
Ear drops and cutaneous suspension
for dogs, cats and guinea pigs

Date: 31 Aug. 2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0321/001/DC
Name, strength and pharmaceutical form	Ototop ear drops and cutaneous suspension
Applicant	LIVISTO Int'l, S.L. Av. Universitat Autònoma 29 08290 Cerdanyola del Vallès (Barcelona) SPAIN
Active substance(s)	Miconazol nitrate Prednisolone acetate Polymyxin B sulfate
ATC Vetcode	QS02CA01
Target species	Dogs, Cats, Guinea Pigs
Indication for use	For the treatment of infection of external auditory canal (otitis externa) in dogs and cats as well as primary and secondary infections of the skin and skin adnexa (hair, nails, sweat glands) in dogs, cats and guinea pigs, caused by the following miconazole and polymyxin B susceptible pathogens: • Fungi (including yeasts) - *Malassezia pachydermatis* - *Candida* spp. - *Microsporum* spp. - *Trichophyton* spp. • Gram-positive bacteria - *Staphylococcus* spp. - *Streptococcus* spp. • Gram-negative bacteria

	- *Pseudomonas* spp. - *Escherichia coli* • For the adjunct treatment of an infestation with *Otodectes cynotis* (ear mites) associated with Otitis externa.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic ´hybrid´ application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	04 March 2020
Date product first authorised in the Reference Member State (MRP only)	N.A.
Concerned Member States for original procedure	AT, BE, CY, CZ, EE, EL, ES, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK

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.
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 safety and efficacy aspects of this product are identical to the reference product Surolan, Lilly Deutschland GmbH Abteilung Elanco Animal Health, which has been authorised in Germany according to the Acquis in April 2005 and Surolan, which has been licensed in Austria in 1978 as part of the same global marketing authorisation. The initial applications for Surolan as authorised in Austria and Germany were assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 23 mg/ml Miconazol nitrate, 5 mg/ml Prednisolone acetate, 5 500 IU /ml Polymyxin B sulfate as the active substances and the following excipients: Anhydrous colloidal silica and liquid paraffin.

The container/closure system is a LDPE bottle closed with screw cap and separate drop dispenser. The bottle is placed in a cardboard box. 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 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 on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substances are Miconazol nitrate, Prednisolone acetate and Polymyxin B sulfate. These are established substances described in the European Pharmacopoeia. The active substances are 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.

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

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 have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substances 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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, results of pharmacokinetic or toxicological tests are not required.

The safety aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment 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.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

This is a hybrid generic application according to Article 13 (3) as amended. Pharmaceutical equivalence with the reference product has been accepted, and efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

Due to the nature of the application, no additional data were required for this section.

Resistance

Due to the nature of the application, no additional data were required for this section. Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Due to the nature of the application, no additional data were required for this section.

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.

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 Heads of Veterinary Medicinal Agencies website (www.hma.eu).

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.

Quality changes

Summary of change **(Application number)**	**Section updated in part II**	**Approval date**
Change in the shelf-life of the finished product: Shelf life extension from 18 months to 2 years (DE/V/0321/001/IB/001)	II.F.2	07.08.2020
Change in the shelf-life of the finished product: Shelf life extension from 2 years to 3 years (DE/V/0321/001/IB/003)	II.F.2	25.08.2021