Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Gerichtstraße 49
13347 Berlin
(Germany)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Otomicol ear drops and cutaneous suspension

Date: 08 May 2024

PRODUCT SUMMARY

EU procedure number	DE/V/0342/001/DC
Name, strength and pharmaceutical form	Otomicol, ear drops and cutaneous suspension
Applicant	KRKA tovarna zdravil d.d. Novo mesto Smarjeska Cesta 6 Novo Mesto 8501 Jugovzhodna Slovenija Slovenia
Active substance(s)	Miconazole nitrate, prednisolone acetate, polymyxin B sulfate
ATC vetcode	QS02CA01
Target species	Dogs, cats, guinea pigs
Indication for use	For the treatment of primary and secondary infections of skin (eczema, dermatitis, pyoderma) and skin adnexa (hair, claws, sweat glands) in dogs, cats and guinea pigs, as well as for the treatment of otitis externa in dogs and cats, caused by infections with the following miconazole and polymyxin B susceptible pathogens: Gram-positive bacteria – *Staphylococcus* spp. – *Streptococcus* spp. Gram-negative bacteria – *Pseudomonas* spp. – *Escherichia coli* Yeasts and fungi – *Malassezia pachydermatis* – *Candida* spp. – *Microsporum* spp. – *Trichophyton spp.* –

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Application in accordance with Article 19 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Surolan
Marketing authorisation holder	Elanco GmbH
MS where the RP is or has been authorised	Germany
Marketing authorisation number	6762218.00.00
EU procedure number	n.a.
Date of authorisation	1979, 29.04.2005
Date of completion of the original decentralised procedure	8 May 2024
Concerned Member States for original procedure	BE, BG, CZ, EE, ES, FR, EL, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI)
Concerned Member States for subsequent recognition procedure	n.a.
Withdrawn CMS during original decentralised procedure	n.a.

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains 23 mg miconazole nitrate, 5500 IU polymyxin B sulfate and 5 mg prednisolone acetate as active substances and the excipients colloidal anhydrous silica and liquid paraffin.

The container/closure system is presented in 15 ml white LDPE bottles with white LDPE dropper and white HDPE closure. The secondary packaging is a printed carton.

The choice of the formulation is justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substances miconazole nitrate, polymyxin B sulfate and prednisolone acetate, are established substances described in the European Pharmacopeia. 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 material. Batch analytical data demonstrating compliance with the specifications have been provided.

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

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

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 tests

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 VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of safety tests are not required.

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

Warnings and precautions as listed in the product literature are comparable to those of the reference VMP. A warning in respect to children has been added. The safety phrases are adequate to ensure safety of the product to the user and the environment.

A. Safety tests

This application has been submitted in accordance with Article 19(1) of Regulation (EU) 2019/6). As essential similarity is accepted and safety has been evaluated for the reference product, the applicant is not required to provide safety data.

Development of resistance and related risk in humans

The applicant has provided bibliographical information regarding the level of resistance in target pathogens which show that the prevalence of resistance remains acceptable across the EU.

Warnings and precautions as listed on the product literature are adequate to ensure prudent and responsible use of the VMP.

In comparison to the reference product, no increase in environmental exposure and no change in the risk of resistance development is to be expected associated with the use of Otomicol, ear drops and cutaneous suspension.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. However, this veterinary medicinal product is a hybrid generic product of the reference product Surolan with the same qualitative and quantitative composition, the same pharmaceutical form, intended to be used in the same species, for the same indications and in the same doses. Therefore, the user safety of Miconazole/Prednisolone/Polymyxin ear drops, suspension is considered the same as those of its reference product. However, an unacceptable risk to children has been identified for miconazole and prednisolone following accidental ingestion of 1.5 ml of the product which is 10% of the bottle (without a child resistant closure). A special warning for children was therefore added.

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

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 VMP will only be used in non-food animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

No pre-clinical studies were performed.

Pharmacology

An exemption from the need to conduct *in vivo* bioequivalence studies in the target species was accepted in accordance with section 7.1 of the CVMP Guideline on the conduct of bioequivalence studies.

Development of resistance and related risk in animals

The applicant has provided bibliographical information regarding the level of resistance in target pathogens which show that the prevalence of resistance in target pathogens remains acceptable across the EU.

Warnings and precautions as listed on the product literature are adequate to ensure prudent and responsible use of the VMP.

Tolerance in the target species of animals

This application has been submitted in accordance with Article 19(1) of Regulation (EU) 2019/6).

As essential similarity is accepted and target animal safety (TAS) has been evaluated for the reference product, the applicant is not required to provide TAS data.

The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

No clinical trials were performed.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

None