Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cefenidex CA/DEX 2 mg + 1 mg/ml eye drops, solution

Date: 10 July 2024

PRODUCT SUMMARY

EU procedure number	DE/V/0343/001/MR
Name, strength and pharmaceutical form	Cefenidex CA/DEX 2 mg + 1 mg/ml eye drops, solution
Applicant	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf
Active substance(s)	Chloramphenicol, Dexamethasone sodium phosphate
ATC vetcode	QS01CA01
Target species	Cats, dogs
Indication for use	Treatment of inflammatory and allergic eye diseases such as conjunctivitis, keratitis, mild iritis and inflammation of the lacrimal sac associated with bacterial infections.

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)	Oftan Dexa-Chlora eye drops, solution
Marketing authorisation holder	Santen Oy
MS where the RP is or has been authorised	Finland
Marketing authorisation number EU procedure number	7089
Date of authorisation	16.07.1975
Date of completion of the original mutual recognition procedure	10 July 2024
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	14 December 2018
Concerned Member States for original procedure	AT, BE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LV, NL, NO, PL, PT, SE, UK(NI)
Concerned Member States for subsequent recognition 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 2.0 mg chloramphenicol and 1.32 mg dexamethasone sodium phosphate as active substances per ml and the excipients benzalkonium chloride, boric acid, borax, disodium edetate, polysorbate 20 and water for injection.

The container/closure system is presented in 10 ml LDPE bottles with a colourless LDPE dropper and a white HDPE closure. The secondary packaging is a cardboard box.

The choice of the formulation and presence of preservative are 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 chloramphenicol and dexamethasone are established active 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 is identical to the reference VMP.

However, warnings and precautions as listed on the product literature are extended compared with the reference VMP. Safety phrases include now the hypersensitive potentials of benzalkonium chloride, dexamethasone and chloramphenicol and possible adverse effects on reproduction (dexamethasone, chloramphenicol). They are adequate to ensure safety of the product to the user and the environment.

A. Safety tests

Pharmacological / toxicological studies

As essential similarity is accepted and pharmacology/toxicology have been evaluated for the reference product, the applicant is not required to provide data.

Observations in humans

The applicant has provided information derived from Martindale, updated in 2023, which show no new, unknown adverse effects were included in this update.

Development of resistance and related risk in humans

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

User safety

The applicant has provided a user risk assessment in compliance with the relevant guideline. The product will be administered by the pet owner who is a non-professional user. Pregnant woman and young children are considered the most sensitive populations. Safety phrases include the hypersensitive potentials of benzalkonium chloride, dexamethasone and chloramphenicol and possible adverse effects on reproduction (dexamethasone, chloramphenicol). Warnings and precautions as listed in 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. Based on the data provided, the VMP is not expected to pose a risk for the environment when used according to the SPC.

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