SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepfenicol 5 mg/ml eye drops, solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:
Chloramphenicol: 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride	0.040 mg
Boric acid	
Borax	
Polysorbate 80	
Water for injections	

Clear, colourless to slightly yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Dog and cat

3.2 Indications for use for each target species

Treatment of bacterial eye infections such as conjunctivitis, keratitis, dacryocystitis and blepharitis.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Before starting treatment, it should be ensured that there are no mechanical or physical causes for the eye inflammation e.g. ectopic cilium, entropion, foreign body, deficiency in tear secretion.

Cross-resistance has been shown between chloramphenicol and others phenicols. Use of the product should be carefully considered when susceptibility testing has shown resistance to phenicols because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Chloramphenicol and benzalkonium chloride can cause allergic reactions. People with known hypersensitivity to chloramphenicol and/or benzalkonium chloride should only administer the veterinary medicinal product with disposable gloves.
In humans, there is evidence that exposure to chloramphenicol may increase the risk of severe aplastic anaemia.
It is therefore essential to avoid skin and eye contact and wash hands after administration of the veterinary medicinal product. In case of accidental skin or eye contact, flush with plenty of water. In the event of hypersensitivity reactions, seek medical advice and show the package leaflet or the label to the physician.
Chloramphenicol may cause serious harm to the unborn child and children who are breastfed. The veterinary medicinal product should therefore not be administered by pregnant and breastfeeding women.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog and cat:

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction Corneal opacity[1]

[1]superficial, temporary

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national

competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product during pregnancy and lactation has not been established.
Chloramphenicol can cross the placenta and pass into milk. Effects on fetuses or suckling puppies and kittens are unlikely, but the veterinary medicinal product should only be used according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Ocular use.
Put one drop (one drop contains 0.15 mg chloramphenicol) in the conjunctival sac of the affected eye, if necessary in both eyes; initially 6-8 times a day, then 4-6 times a day. Severe eye disease may require more frequent dosing (one drop every 1-2 hours) for the first 24-48 hours. Treatment should be continued for 2 days after symptoms have subsided.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

With local application an overdose is very unlikely.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QS01AA01

4.2 Pharmacodynamics

Chloramphenicol is a broad-spectrum antibiotic whose spectrum of activity includes gram-positive and gram-negative aerobic and anaerobic bacteria as well as

chlamydia and mycoplasma. Chloramphenicol binds to the 50S subunit of the bacterial ribosome and prevents transpeptidation during bacterial protein synthesis. The action of chloramphenicol is primarily bacteriostatic. Chloramphenicol shows no significant activity against *Pseudomonas aeruginosa*.

The most commonly reported mechanism of resistance for chloramphenicol is enzymatic inactivation by chloramphenicol acetyltransferases (CATs). Acetylation prevents chloramphenicol from binding to the 50S subunit of the bacterial ribosome. Genes encoding CAT are often located on mobile elements such as plasmids, transposons or gene cassettes.

Several other resistance mechanisms through efflux systems, inactivating phosphotransferases and mutations in target sites are described.

There is cross-resistance between substances of the phenicol class. For instance, in gram-negative bacteria the *flo*R gene located on a plasmid promotes efflux of chloramphenicol and florfenicol. In gram-positive cocci, *fex*A has been found which encodes an efflux pump conferring resistance to florfenicol and chloramphenicol. Additionally, a multi-resistance genes *cfr* has been identified that can be located on plasmids or transposons which confers resistance by the rRNA methyltransferase to pleuromutilins, oxazolidinones, phenicols, streptogramin A, and lincosamides.

4.3 Pharmacokinetics

Chloramphenicol is a fat-soluble substance. When applied locally, it is well absorbed into the mucous membrane and the aqueous humor. Chloramphenicol is metabolized in the liver to inactive glucuronide and excreted primarily (80-90%) in the urine. The elimination half-life in plasma is 2-4 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2°C – 8°C).
After first opening the container, store below 25°C.
Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless LDPE dropper container, and a white HDPE screw cap.

Pack size:
Cardboard box with 1x10 ml dropper container.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.
Medicines should not be disposed of via wastewater or household waste.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER

Vm 20916/3019

8. DATE OF FIRST AUTHORISATION

21 August 2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 21 August 2024