

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Outer carton

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cepfenicol 5 mg/ml Eye drops, Solution for Dogs and Cats

**2. STATEMENT OF ACTIVE SUBSTANCES**

Chloramphenicol 5.0 mg/ml

**3. PACKAGE SIZE**

10 mL

**4. TARGET SPECIES**

Dog and cat

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Ocular use.

Put one drop 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. The frequency of administration of the drops and the duration of treatment depends on the disease and the response to therapy. Treatment should be continued for 2 days after symptoms have subsided.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. mm/yyyy

Once broached, use within 28 days – use by: \_\_\_\_\_.

**9. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator.

After first opening the container, store below 25°C.

Keep the container in the outer carton in order to protect from light.

**10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"**

Read the package leaflet before use.

**11. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

CP Pharma Handelsgesellschaft mbH

**14. MARKETING AUTHORISATION NUMBERS**

Vm 20916/3019

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Bottle**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cepfenicol

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Chloramphenicol 5.0 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 28 days.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Cepfenicol 5 mg/ml Eye drops, Solution for Dogs and Cats

### 2. Composition

Each mL of contains:

**Active substance:**

Chloramphenicol: 5.0 mg

**Excipient:**

Benzalkonium chloride: 0.040 mg

Clear, colourless to slightly yellowish solution.

### 3. Target species

Dog and cat

### 4. Indications for use

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

### 5. Contraindications

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

### 6. Special warnings

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.

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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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.

Interaction with other medicinal products and other forms of interaction:

No data available.

Overdose:

With local application an overdose is very unlikely.

Major incompatibilities:

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

## **7. Adverse events**

Dog and cat:

Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction Corneal opacity <sup>1</sup>
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<sup>1</sup>superficial, temporary

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing



authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## **8. Dosage for each species, routes and method of administration**

Ocular use.

Dog and cat:

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.

## **9. Advice on correct administration**

See section: "Dosage for each species, routes and method of administration".

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "Exp.". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

#### **14. Marketing authorisation numbers and pack sizes**

Vm 20916/3019

Cardboard box with 1x10 ml dropper container.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

CP-Pharma Handelsgesellschaft mbH  
Ostlandring 13  
31303 Burgdorf

Local representatives and contact details to report suspected adverse reactions:

{To be completed nationally.}

#### **17. Other information**

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Approved: 21 August 2024