SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Chloramphenicol 1% w/w eye ointment
Chlorop eye ointment

2. Qualitative and quantitative composition
Each gram of ointment contains 10 mg of chloramphenicol.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Eye ointment.

A white, smooth, soft, homogeneous sterile ointment.

4. Clinical particulars

4.1 Therapeutic indications
Chloramphenicol is indicated for the treatment of acute bacterial conjunctivitis in adults and children aged 2 years and over.

4.2 Posology and method of administration
Adults (including elderly people) and children aged 2 years and over:
If using just the eye ointment, apply about 1 cm of ointment to the affected eye(s) 3 to 4 times a day.

If using chloramphenicol eye drops during the day and the eye ointment at night - apply the ointment at night, before going to bed.

The course of treatment is 5 days.

Method of administration
For ocular use.
The ointment is applied to the space between the lower eyelid and the eye.

4.3 Contraindications
Hypersensitivity to the active substance or any of the excipients listed in section 6.1.
Patients who have experienced myelosuppression during previous exposure to chloramphenicol.
Family or personal history of blood dyscrasias including aplastic anaemia.

4.4 Special warnings and precautions for use
Chloramphenicol is absorbed systemically from the eye and toxicity has been reported following chronic exposure.

Bone marrow hypoplasia, including aplastic anaemia and death, has been reported following topical use of chloramphenicol. Whilst the hazard is a rare one, it should be borne in mind when assessing the benefits expected from the use of the compound. Where chloramphenicol antibiotic eye ointment is used on a long-term or intermittent basis, it may be advisable to

perform a routine blood profile before therapy and at appropriate intervals thereafter to detect haemopoietic abnormalities.

In severe bacterial conjunctivitis and in cases where infection is not confined to the conjunctivae, the topical use of chloramphenicol should be supplemented by appropriate systemic treatment. Therefore, the patient should be referred to seek medical advice.
The use of topical chloramphenicol may occasionally result in the overgrowth of non-susceptible organisms including fungi. If any new infection appears during treatment, the patient should be referred to the doctor.

Prolonged use of chloramphenicol eye drops is not advisable, as it may increase the likelihood of sensitisation and emergence of resistant organisms. If any new infection appears during treatment, the antibiotic should be discontinued and appropriate measures taken.
Chloramphenicol should be reserved for use only for infections for which it is specifically indicated.

Chloramphenicol does not provide adequate coverage against *Pseudomonas aeruginosa* and *Serratia marcescens*.

Chloramphenicol eye ointment should not be used for more than 5 days at a time except on the advice of a doctor. Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms worsen at any time.

Chloramphenicol eye ointment should not be recommended under the following circumstances (in these circumstances patients should be referred to their doctor):
• Severe pain in the eye
• Disturbed vision
• Photophobia
• Eye inflammation associated with a rash on the scalp or face
• The pupil looks unusual
• The eye looks cloudy
• Suspected foreign body in the eye.

Patients should also be referred to their doctor if any of the following in his/her medical history apply:
• Associated pain or swelling around the eye or face
• The patient has had conjunctivitis previously in the recent past
• The patient has glaucoma
• The patient has dry eye syndrome
• The patient has an eye injury
• The patient is already using other eye ointments or eye drops.
• The patient has had eye surgery or laser treatment in the last 6 months.

If the patient wears contact lenses, they should seek advice either from their contact lens practitioner (optician, optometrist) or doctor before using this product. Contact lenses should not be worn during the course of treatment.

4.5 Interaction with other medicinal products and other forms of interaction
The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided.

4.6 Pregnancy, fertility and lactation
The safety of topical chloramphenicol in pregnancy and lactation has not been established. Chloramphenicol may be absorbed systemically following the use of the eye ointment. Chloramphenicol does cross the placenta and enter breast milk. Therefore, use only when considered essential by the physician.

4.7 Effects on the ability to drive and use machines
Chloramphenicol may cause transient blurring of vision on instillation of the ointment. The user should not drive or operate hazardous machinery unless the vision is clear.

4.8 Undesirable effects
Transient burning or stinging sensations may occur with the use of chloramphenicol. More serious side effects include bone marrow depression and rarely aplastic anaemia, angioneurotic oedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported and are causes for discontinuation.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Adverse Drug Reaction (ADR)/ Serious Adverse Event (SAE) electronic form linked to the MCAZ database using the following link: https://primaryreporting.who-umc.org/ZW.

4.9 Overdose
Accidental ingestion of chloramphenicol is unlikely to cause systemic toxicity due to the low content of the antibiotic. If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated for at least 15 minutes. If symptoms persist after this, an ophthalmological examination should be considered.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacological classification: 7.2.5 Other Antibacterials.

Chloramphenicol is a broad-spectrum antibiotic which has activity against many types of Gram-positive and Gram-negative bacteria. Chloramphenicol is not effective against fungi, protozoa, and viruses.

Acute bacterial conjunctivitis is commonly caused by staphylococci or streptococci in adults, and *Haemophilus influenzae* and *Moraxella catarrhalis* (formerly known as *Branhamella catarrhalis*), particularly in children.

Chloramphenicol is effective against Gram-positive cocci including staphylococci such as *Staph. epidermidis* and some strains of *Staph. aureus*, and streptococci such as *S.pneumoniae*, *S.pyogenes*, and the viridans streptococci.

Gram-negative cocci such as *Haemophilus influenzae* are usually highly sensitive. *Moraxella catarrhalis,* a Gram-negative aerobic diplococcus frequently found as a commensal of the upper respiratory tract, is also highly sensitive.

5.2 Pharmacokinetic properties
Evidence suggests that chloramphenicol is absorbed systemically via topical ocular administration. Any chloramphenicol that is absorbed will be widely distributed in the body tissues and fluids. It is found in cerebrospinal fluid, giving concentrations of about 50% of those existing in the blood even in the absence of inflamed meninges; it diffuses across the placenta into the fetal circulation, into breast milk and the aqueous and vitreous humour of the eye; it is also secreted in saliva, with the highest concentrations occurring in the kidneys and liver. Up to about 60% of the circulation is bound to plasma protein.

Chloramphenicol is excreted chiefly in the urine as the glucuronide with small amounts being excreted via the bile and faeces. It has a reported half-life of 1.5 to 4 hours which is increased in patients with liver impairment and neonates to between 24 and 28 hours in the latter. Renal impairment has relatively little effect on the half-life of the active drug, due to its extensive metabolism, but may lead to accumulation of the inactive metabolites. Chloramphenicol is excreted mainly in urine.

The absorption, metabolism, and excretion of chloramphenicol are subject to considerable interindividual variation, especially in infants and children, making monitoring of plasma concentrations necessary to determine pharmacokinetics in a given patient.

5.3 Preclinical safety data
Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients
Microcrystalline wax
White soft paraffin

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of the container
An aluminium collapsible tube.

Fill weight: 5 g.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT
Cospharm Investments (Pty) Ltd
ERF 492 Dante Street
Prosperita
Windhoek
Namibia

8. MANUFACTURER
SM Pharmaceutical Sdn Bhd
Lot 88, Sungai Petani Industrial Estate
08000 Sungai Petani
Kedah Darulaman
Malaysia

9. REGISTRATION DETAILS
Zimbabwe registration number: 2023/7.2.5/6537
Zimbabwe category for distribution: Prescription Preparations (P.P.)

10. DATE OF REVISION OF THE TEXT
March 2024