NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Chloramphenicol 1% w/w Eye Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Chloramphenicol Eye Ointment contains 1% w/w chloramphenicol.

Excipient with known effect:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.
A yellowish-white, translucent greasy ointment, free of visible contamination in aluminum tubes.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of bacterial conjunctivitis. For use under medical supervision only in the treatment of other superficial ocular infections caused by chloramphenicol-sensitive organisms.

4.2 Dose and Method of Administration

Posology/duration and frequency of administration

For adults and children (2 years and over): Apply 1.5 cm into lower eye lid of the affected eye every three hours for up to 5 days. To minimize contamination do not allow the tip to contact the surface of the eye.

Treatment should be continued for at least 48 hours after the eye appears normal.

Method of administration
Topical administration to the eye only.
To minimize contamination do not allow the tip to contact the surface of the eye.

Additional information on special populations

Hepatic/Renal impairment
No dosage adjustment is required in patients with impaired hepatic or renal function.

Pediatric population
Chloramphenicol is not recommended for children under 2 years except on medical advice.

Geriatric population
There is no indication that dosage needs to be modified for the elderly.

4.3 Contraindications

Chloramphenicol is contraindicated in individuals with a history of hypersensitivity to any excipients and/or toxic reaction to the medicine.

4.4 Special warning and precautions for use

Bone marrow hypoplasia, including aplastic anemia and death, has been rarely reported following local application of chloramphenicol.
Chloramphenicol should not be used when less potentially dangerous agents would be expected to provide effective treatment. Ophthalmic agents may retard corneal wound healing.

The use of this antibiotic, as with other antibiotics, may result in the overgrowth of non-susceptible organisms, including fungi. If infections caused by non-susceptible organisms appear during therapy, its use should be discontinued and appropriate measures should be taken. In all serious infections, the topical use of chloramphenicol should be supplemented by appropriate systemic medication.

The mechanism for the irreversible aplastic anemia following ophthalmic use of chloramphenicol has not been established.

Chloramphenicol ointment should not be recommended for OTC use under the following circumstances:

- Photophobia
- Severe pain in the eye or pain and swelling around the eye
- Loss of, reduced or blurred vision
- Restriction of eye movement
- Cloudy cornea
- Copious yellow-green purulent discharge that accumulates after being wiped away
- Contact lens wear
- Abnormal pupils
- Injury to the eye or suspicion of a foreign body in the eye
- History of welding without eye protection immediately prior to onset of symptoms
- Glaucoma
- Dry eye syndrome
- Patient is a contact lens user
- Patient is using other eye drops or eye ointments at the time of presentation
- Patient has had eye surgery or laser treatment in the past six months
- Individual or family history of bone marrow problems
- Recent overseas travel
- Patient has had similar symptoms in the past
- Patient feels unwell

In these cases, referral to a doctor or optometrist is required.

Instructions to Patients

- If symptoms worsen at any time or if the eye infection does not improve within 48 hours, seek prompt medical advice.
- Patients who wear contact lenses should be advised to seek advice from their doctor or optometrist before using Chloramphenicol ointment. Contact lenses should not be worn during the course of Chloramphenicol treatment. If wearing **hard** or **disposable** contact lenses, patients can start using their lenses again after successfully completing the course of treatment. If wearing **soft** contact lenses, patients should wait 24 hours after successfully completing a course of treatment before starting to use their lenses again.

4.5 Interaction with other medicinal products and other forms of interaction

Not available.

4.6 Fertility, pregnancy and lactation

General recommendation
Pregnancy category is C.

Women with child-bearing potential/Contraception
Animal studies are insufficient with respect to effects on pregnancy /and-or/ embryonal/fetal development/ and-or/ parturition/ and-or/ postnatal development (see section 5.3). The potential risk for humans is unknown.

Pregnancy & Breast-feeding
Systematically absorbed/administered forms of chloramphenicol enter the fetal circulation and are distributed into breast milk. If given systematically to the mother shortly before parturition or whilst breastfeeding, chloramphenicol may cause bone marrow suppression of the neonate or the "grey baby syndrome", characterized by cyanosis and hypothermia, owing to the limited glucuronidating capacity of the neonate's liver. However, limited absorption following ophthalmic use at the recommended dosage is generally not expected to pose a risk to the fetus or neonate.

Fertility
There is insufficient data for chloramphenicol on human or nonclinical fertility studies.

4.7 Effects on ability to drive and use machines
Patients experiencing blurred vision or other visual disturbances should refrain from driving a vehicle or operating machines until vision clears.

4.8 Undesirable effects
Blood dyscrasias have been reported in association with the use of chloramphenicol (see section 4.4). Chloramphenicol is absorbed systemically from the eye, and toxicity has been reported following chronic exposure. Dose related toxicity following a single ocular exposure is unlikely. Local irritation with the ophthalmic form may include subjective symptoms of itching or burning. More serious side effects such as angioneurotic edema; anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported in patients sensitive to chloramphenicol and are causes for discontinuing the medication. Similar sensitivity reactions to other materials in topical preparations also may occur.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose
Accidental overdose or accidental ingestion of the ointment is unlikely to cause systemic toxicity due to low content of chloramphenicol in the product.

Treatment
If irritation, pain, swelling, lacrimation or photophobia occur after undesired eye contact, the exposed eye(s) should be irrigated with copious amounts of room temperature water for at least 15 minutes. If symptoms persist after 15 minutes of irrigation, an ophthalmological examination should be considered.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ophtalmologicals, antibiotics
ATC code: S01AA01

Chloramphenicol is a broad spectrum antibiotic originally isolated from *Streptomyces venezuelae*. It is primarily bacteriostatic and acts by inhibition of protein synthesis by interfering with the transfer of activated amino acids from soluble RNA to ribosomes.

5.2. Pharmacokinetic properties

Absorption
Chloramphenicol is found in measurable amounts in the aqueous humor following local application to the eye. Systemic exposure to chloramphenicol occurs at a very low level after topical ophthalmic use.

5.3 Preclinical safety data

Pre-clinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin liquid
Paraffin soft white

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.
Discard 4 weeks after opening.

6.4 Special precautions for storage

Store at or below 25°C.
Keep out of the reach and sight of children.

6.5 Nature and contents of container

Lacquered aluminium tube with HDPE cap containing 5 g ophthalmic ointment.

6.6. Special precautions for disposal

No special requirements for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Pharmacist-Only Medicine.

8. SPONSOR

DEVATIS LIMITED
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New Zealand

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9. DATE OF FIRST APPROVAL

Date of first authorization: 25 July 2019
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT

September 2024