NEW ZEALAND DATA SHEET

1. OCUZO 0.5% w/v EYE DROPS

Chloramphenicol 5 mg/mL (0.5% w/v) eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloramphenicol 0.5% w/v

For the full list of excipients, see **Section 6.1 List of excipients**.

3. PHARMACEUTICAL FORM

Eye drops

OCUZO eye drops consist of a clear to slightly hazy colourless, slightly viscous liquid and odourless solution.

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

For adults and children (2 years and over): Place 1 or 2 drops in the affected eye(s) every two to six hours, for two to three days. The interval between applications may then be increased. Normally treatment is continued for at least two days after the eye appears normal. Do not use for more than five days in total except on medical advice. To minimise contamination do not allow the dropper to contact the surface of the eye. Discard solution within one month of opening container.

OCUZO eye drops are not recommended for children under 2 years except on medical advice.

If used in children under 2 years of age, the following is the recommended dosage: One drop in the affected eye(s) four times daily for five days.

The systemic absorption of OCUZO eye drops can be minimised by applying gentle pressure on the tear-duct for approximately one minute immediately after application.

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 warnings and precautions for use

Bone marrow hypoplasia, including aplastic anaemia 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 anaemia following ophthalmic use of chloramphenicol has not been established.

Chloramphenicol eye drops 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 OCUZO. Contact lenses should not be worn during the course of OCUZO 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 medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Systematically absorbed/administered forms of chloramphenicol enter the foetal 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”, characterised 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 foetus or neonate.

Excipients containing boron have been shown to cause reduced fertility and effects on embryofoetal development in animal studies and this appears to be dose related. The relevance of this to humans is uncertain.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

OCUZO eye drops have no influence on the ability to drive and use machines.

4.8 Undesirable effects

Blood dyscrasias have been reported in association with the use of chloramphenicol (see Warnings and Precautions). 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 oedema; 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 authorisation 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 ingestion of the medicine is unlikely to cause any toxicity due to low content of antibiotic. OCUZO eye drops contain borax/boric acid as buffer and sodium hydroxide. If the eye drops are accidentally ingested by infants or young children, Poisons Information Centre (Telephone: 0800 764 766) should be contacted. The medication should be kept out of reach of children.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

No data available.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

OCUZO eye drops contain the following excipients:
Boric acid
Borax
Sodium hydroxide and/or
Hydrochloric acid
Water for injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months from the date of manufacture.

6.4 Special precautions for storage

Store between 2 – 8 °C. Refrigerate. Do not freeze.
After opening, store at or below 25 °C.
Discard bottle 4 weeks after opening.
Protect from light.

6.5 Nature and contents of container

10 mL OCUZO eye drops solution is packed into a 11 mL multidose LDPE Novelia ® dropper bottle.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Restricted Medicine

8. SPONSOR

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9. DATE OF FIRST APPROVAL

13 May 2021

10. DATE OF REVISION OF THE TEXT

26 November 2021

Date	Section(s) Changed	Change(s)
November 2021	4.2 and 4.6	Addition of boron dosage and boron fertility warning.