NEW ZEALAND DATA SHEET

1. PRODUCT NAME
CHLORAFAST, Eye drops, solution, 0.5 %w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each mL contains 5mg of chloramphenicol equivalent to 0.5%w/v.

Excipient with known effect: phenyl mercuric nitrate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Eye drops, solution.

CHLORAFAST is a colourless to faint yellow aqueous solution.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of bacterial conjunctivitis and other superficial ocular infections caused by chloramphenicol-sensitive organisms.

4.2 Dose and method of administration
Adults and children (including the Elderly)
Instil 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.

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

Information for patients
In order to minimise systemic absorption of CHLORAFAST eye drops, apply gentle pressure to the tear duct for approximately one minute immediately after application.

Care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle.

Do not touch dropper tip to any surface, as this may contaminate the solution.

4.3 Contraindications
CHLORAFAST is contraindicated in individuals with a history of hypersensitivity to any excipients and/or toxic reaction to the medicine (refer section 6.1).

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.

Contact lenses should be removed during the period of treatment.

This product is not intended for long term treatment of dry eye syndrome.

4.5 Interaction with other medicines and other forms of interaction

Chymotrypsin may be inhibited if given simultaneously with chloramphenicol.

No specific interactions or incompatibilities with other opthalmically administered medicines are known.

4.6 Fertility, pregnancy and lactation

Pregnancy Category A

Chloramphenicol enters the foetal circulation, and if given to the mother shortly before parturition, may cause the *gray baby syndrome*, with cyanosis and hypothermia, owing to the limited glucoronidating capacity of the newborn infant's liver.

Use in Lactation

Chloramphenicol treatment should, therefore, be avoided during the last week before parturition and during breast feeding.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Patients should be warned not to drive or operate machines unless vision is clear.

4.8 Undesirable effects

Blood dyscrasias have been reported in association with the use of chloramphenicol (see section 4.4 Special warnings and precautions for use).

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. Each mL of CHLORAFAST eye drops contains 19 mg of borax/boric acid as buffer and if accidentally ingested by infants or young children, the National Poisons Centre should be contacted. It is advisable to keep medication out of reach of children.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, Anti-infectives, Antibiotics, ATC code: S01AA01

Chloramphenicol is a broad spectrum antibiotic which acts through the inhibition of bacterial protein synthesis by preventing attachment of aminoacyl transfer RNA to its acceptor site on the ribosome. It is bacteriostatic and is effective against a wide range of Gram-positive and Gram-negative bacteria, as well as some other organisms.

5.2 Pharmacokinetic properties

Chloramphenicol is readily absorbed from the gastro-intestinal tract when given orally and is widely distributed in body tissues and fluids.

Chloramphenicol is excreted mainly in the urine but only 5 to 10% of an oral dose appears unchanged; the remainder is inactivated in the liver, mostly by conjugation with glucuronic acid.

Following instillation into the eye the levels in the aqueous humor are in the same order as seen following oral administration with levels in the region 5mcg/mL being seen after repeated applications of 0.5% drops in humans.

5.3 Preclinical safety data

No information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenyl mercuric nitrate (0.002% w/v), Borax, Boric acid and Water for Injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life: 2 years.
Discard contents 28 days after first opening the bottle.

6.4 Special precautions for storage

Before opening: Store between 2ºC and 8°C. Refrigerate, do not freeze. Protect from light.

After opening: Store below 25°C. Protect from light.

6.5 Nature and contents of container

Plastic dropper bottles with a polystyrene cap. Each bottle has a fill volume of 10 mL.

6.6 Special precautions for disposal

None.

7. MEDICINE SCHEDULE

Pharmacist Only Medicine

8. SPONSOR

Teva Pharma (New Zealand) Limited
PO Box 128244
Remuera
Auckland 1541
Telephone: 0800 800 097

9. DATE OF FIRST APPROVAL

16 August 2007

10. DATE OF REVISION OF THE TEXT

12 January 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
	Update to the SPC-style format