1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

CHLORAMEX OPHTHALMIC OINTMENT

COMPOSITION

Each 1 g of CHLORAMEX OPHTHALMIC OINTMENT contains 10 mg of chloramphenicol.

Excipients: Hard paraffin, liquid paraffin, wool fat, yellow soft paraffin.

CATEGORY AND CLASS

A 15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Chloramphenicol is a broad spectrum antibiotic with bacteriostatic and bactericidal properties (depending on concentration) against a wide range of pathogenic organisms, including Gram-positive and Gram-negative bacteria, rickettsiae and the trachoma virus.

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

INDICATIONS

Superficial infections of the eye and eyelid, including conjunctivitis, uveitis, corneitis, blepharitis and trachoma.

CONTRAINDICATIONS

CHLORAMEX OPHTHALMIC OINTMENT is contraindicated in:

- Patients with hypersensitivity to chloramphenicol or to any of the excipients in CHLORAMEX OPHTHALMIC OINTMENT (see COMPOSITION).
- Patients with a known personal or family history of blood dyscrasias including aplastic anaemia.

WARNINGS AND SPECIAL PRECAUTIONS

For ophthalmic use only.

Do not use if you are allergic to chloramphenicol or any of the ingredients (see CONTRAINDICATIONS)

Hypersensitivity reactions including rashes, fever, and angioedema may occur especially after topical use; anaphylaxis has occurred. Jarisch-Herxheimer reactions may also occur.

Gastrointestinal symptoms including nausea, vomiting, and diarrhoea can follow oral use.

Disturbances of the oral and intestinal flora may cause stomatitis, glossitis, and rectal irritation. Systemically administered chloramphenicol has caused both fatal and non-fatal blood dyscrasias, such as agranulocytosis and aplastic anaemia in a small percentage of cases. It is not considered advisable to use CHLORAMEX OPHTHALMIC OINTMENT in patients with a previous history of such dyscrasia (see CONTRAINDICATIONS).

In severe infections the topical use of chloramphenicol, as found in CHLORAMEX OPHTHALMIC OINTMENT, should be supplemented by appropriate systemic treatment.

Prolonged use of chloramphenicol, as found in CHLORAMEX OPHTHALMIC OINTMENT, should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms. If any new infection appears during treatment, CHLORAMEX OPHTHALMIC OINTMENT should be discontinued and appropriate measures taken. CHLORAMEX OPHTHALMIC OINTMENT should be reserved for use only for infections for which it is specifically indicated.

Medical advice should be sought if there is no improvement in the condition after 2 days or if symptoms worsen at any time, if there is eye injury or current use of other eye drops or eye ointment.

Patients should be advised to consult their doctor if any of the following apply:

- Disturbed vision
- Severe pain within the eye
- Photophobia
- Eye inflammation associated with a rash on the scalp or face
- The eye looks cloudy
- The pupil of the eye looks unusual
- Suspected foreign body in the eye

Patients should be advised to consult their doctor if any of the following in his/her medical history apply:

- Previous conjunctivitis in the recent past
- Glaucoma
- Dry eye syndrome
- Eye surgery or laser treatment in the last 6 months

If a patient wears contact lenses, advice either from a contact lens practitioner (optician, optometrist) or doctor should be sought, before you use CHLORAMEX OPHTHALMIC OINTMENT.

Contact lenses should not be worn during the course of treatment. Soft contact lenses should not be worn for at least 24 hours after finishing using CHLORAMEX OPHTHALMIC OINTMENT.

- If symptoms do not improve within 48 hours your doctor should be consulted.
- Further immediate medical advice should be sought at any time if symptoms worsen.

Effects on ability to drive and use machines

Since adverse reactions such as transient burning, stinging sensations and blurring of vision have been reported in patients receiving CHLORAMEX OPHTHALMIC OINTMENT, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that CHLORAMEX OPHTHALMIC OINTMENT does not adversely affect their ability to do so (see SIDE EFFECTS).

INTERACTIONS

The concomitant administration of CHLORAMEX OPHTHALMIC OINTMENT with other medicines liable to depress bone marrow function should be avoided.

CHLORAMEX OPHTHALMIC OINTMENT is inactivated in the liver and may, therefore, interact

with medicines that are metabolised by hepatic microsomal enzymes.

CHLORAMEX OPHTHALMIC OINTMENT enhances the effects of coumarin anticoagulants, warfarin, some hypoglycaemics such as chlorpropamide and tolbutamide, and antiepileptics such as phenytoin.

The metabolism of CHLORAMEX OPHTHALMIC OINTMENT may be increased by inducers of hepatic enzymes such as phenobarbitone or rifampicin.

Since CHLORAMEX OPHTHALMIC OINTMENT is absorbed systemically, the following interactions is a possibility:

- CHLORAMEX OPHTHALMIC OINTMENT may decrease the effects of iron and vitamin B_{12} in anaemic patients.
- CHLORAMEX OPHTHALMIC OINTMENT may impair the action of oral contraceptives.

HUMAN REPRODUCTION

The safety of CHLORAMEX OPHTHALMIC OINTMENT in pregnancy and lactation has not been established.

Pregnancy

Chloramphenicol, as found in CHLORAMEX OPHTHALMIC OINTMENT, may be absorbed systemically following the use of eye ointment and may cross the placenta.

Lactation

CHLORAMEX OPHTHALMIC OINTMENT may appear in breast milk.

DOSAGE AND DIRECTIONS FOR USE

For ophthalmic use only.

Eye infections

Draw down the lower lid and squeeze a small amount into the corner of the eye and massage gently over the eye surface. Apply four times daily.

Eyelid infections

Apply four times daily to the affected area with the fingertip.

SIDE EFFECTS

Blood and the lymphatic system disorders

Less frequent: Bone marrow depression, aplastic anaemia

Immune system disorders

Less frequent: Anaphylaxis, angio-oedema

Nervous system disorders

Less frequent: Transient burning, stinging sensations

Skin and subcutaneous tissue disorders

Less frequent: Urticaria, vesicular and maculopapular dermatitis

General disorders and administration site conditions

Less frequent: Fever

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

Accidental ingestion of CHLORAMEX OPHTHALMIC OINTMENT is unlikely to cause systemic toxicity due to the low content of the antibiotic.

Treatment

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.

IDENTIFICATION

CHLORAMEX OPHTHALMIC OINTMENT is a translucent pale yellow ointment, with a slightly greasy odour.

PRESENTATION

3,5 g ointment is packed in a printed cylindrical collapsible aluminium tube with an applicator-nozzle, sealed using a white HDPE cap. One tube is placed in a unit cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store in a cool place at or below 25 °C.

Protect from light.

Keep the tube tightly closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H1193 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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