

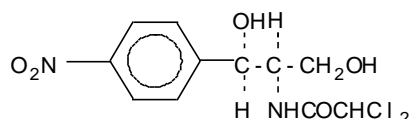
## DATA SHEET

### CHLOROMYCETIN<sup>®</sup> OINTMENT

(chloramphenicol 10 mg per g)

The active component of CHLOROMYCETIN ointment is chloramphenicol.

Structure of chloramphenicol:



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## DESCRIPTION

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Chloramphenicol is a white to greyish-white or yellowish-white, fine crystalline powder or fine crystals, needles or elongated plates. Soluble 1 in 400 of water, 1 in 2.5 of alcohol, and 1 in 7 of propylene glycol; freely soluble in acetone and ethyl acetate; slightly soluble in ether. A 2.5% suspension in water has a pH of 4.5 to 7.5.

**Chemical Name:** 2,2-Dichloro-N-[( $\alpha$ R, $\beta$ R)- $\beta$ -hydroxy- $\alpha$ -hydroxymethyl-4-nitrophenethyl] acetamide.

**Molecular Formula:** C<sub>11</sub>H<sub>12</sub>Cl<sub>2</sub>N<sub>2</sub>O<sub>5</sub>

**Molecular Weight:** 323.1

CHLOROMYCETIN ointment contain chloramphenicol 10 mg per 1 g with plastibase 50W and liquid paraffin.

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## PHARMACOLOGY

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### Actions

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.

### Pharmacokinetics

It has been noted that chloramphenicol is found in measurable quantities in the aqueous humor following local application to the eye. Development of resistance to chloramphenicol can be regarded as minimal for staphylococci and many other species of bacteria.

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## **INDICATIONS**

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Ocular bacterial infections caused by organisms susceptible to chloramphenicol.

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## **CONTRAINDICATIONS**

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CHLOROMYCETIN eye ointment is contraindicated in individuals with a history of hypersensitivity and/or toxic reaction to chloramphenicol or any other component of the medication.

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## **PRECAUTIONS**

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Discontinue promptly if sensitisation or irritation occurs.

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 an 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.

### **Use in 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 glucuronidating capacity of the newborn infant's liver. Chloramphenicol treatment should be avoided during the last week before parturition and during breastfeeding.

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## **ADVERSE REACTIONS**

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Blood dyscrasias have been reported in association with the use of chloramphenicol (see 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.

Superinfection, such as with *Candida* may occur.

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## **DOSAGE AND ADMINISTRATION**

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Apply 1.5cm every three hours. If ointment is used together with drops for day and night coverage, 1.5cm should be applied before retiring, while using the drops during the day. Discard the eye ointment within 1 month of opening the container.

Treatment should be continued for at least two days after the eye appears normal.

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## **OVERDOSAGE**

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Accidental ingestion of the drug is unlikely to cause any toxicity due to the low content of antibiotic. If accidentally ingested by infants or young children, a local Poisons Information Centre should be contacted. It is advisable to keep medication out of reach of children.

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 ophthalmologic examination should be considered.

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## **PRESENTATION**

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Eye Ointment 10mg per g, tube (with tamper seals): 4g

Store below 25°C.

Protect from light.

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## **MEDICINE CLASSIFICATION**

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Prescription Medicine.

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## **SPONSOR**

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Pfizer New Zealand Ltd  
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**DATE OF PREPARATION**

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06 May 2009