SUMMARY OF PRODUCT CHARACTERSTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

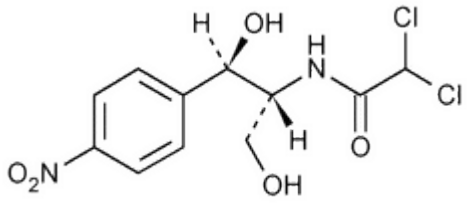
Name of product:Chloramphenicol Eye Ointment.

Strength: 1%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient: Chloramphenicol

Chloramphenicol
(klor" am fen' i kol).



$C_{11}H_{12}Cl_2N_2O_5$ 323.13

Acetamide, ,2-dichloro-*N*-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-,

[*R*-(*R**,*R**)]-. D-*threo*-(−)-2,2-Dichloro-*N*-[β-hydroxy-α

-(hydroxymethyl)-*p*-nitrophenethyl]acetamide [56-75-7].

3. PHARMACEUTICAL FORM

Eye Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Chloramphenicol Eye Ointment 1% is indicated for the treatment of surface ocular infections involving the conjunctiva and/or cornea caused by chloramphenicol-susceptible organisms.

The particular antiinfective dug in this product is active against the following common bacterial eye pathogens:

Staphylococcus aureus

Streptococcus, including Streptococcus pneumonia

Escherichia coli

Haemophilusinfluenzae

Klebsiella/Enterobacter species

Moraxella lucunata

(Morax-Axenfeld bacillus)

Neisseria species

This product does not provide adequate coverage against:

Pseudomonas aeruginosa

Serratiamarcescens

4.2 Posology and method of administration

Apply to the eyelids, generally 3 times a day.

A small amount of ointment placed in the lower conjunctival sac every three hours or more frequently if deemed advisable by the prescribing physician. Administration should be continued day and night the first 48 hours, after which the interval between applications may be increased. Treatment should be continued for at least 48 hours after the eye appears normal.

Newborns and premature infants are prohibited.

Pregnant women and Suckling women should use it with caution

4.3 Contraindications

This product is contraindicated in persons sensitive to any of its components.

4.4 Special warnings and special precautions for use

Bone marrow hypoplasia including aplastic anemia and death has been reported following topical application of chloramphenicol. Chloramphenicol should bot beused when less potentially dangerous agents would be expected to provide effective treatment.

Eye ointment may retard corneal wound healing.

4.5 Interaction with other FPPs and other forms of interaction

Combination with lincomycins and erythromycins and other macrolide antibiotics can cause antagonism, so the combined application is not suitable.

4.6 Pregnancy and lactation

Pregnancy and lactation:

Although this product is topical, it may cause serious adverse reactions to newborns and Suckling infants due to the serious bone marrow inhibition effect of chloramphenicol, so pregnant women and Suckling women should use it with caution

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

May cause eye irritation, allergic reaction, etc

4.9 Overdose

Large doses of long-term use(more than 3 months) can cause optic neuritis or optic

nerve papillitis (especially children).

5. PHARMACOLOGICAL PROPERTIES

Chloramphenicol is a broad-spectrum antibiotic originally isolated from Streptomyces venezuelae. It is primarily bacteriostatic and acts by inhabition o protein synthesis by interfering with the transfer of activated amino acids from soluble RNA to ribosomes. It has been noted that chloramphenicol is found in measurable amounts 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin	3.8gm
Paraffin	0.04gm
White Soft Paraffin	0.12gm

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C, protect from freezing.

6.5 Nature and contents of container

It is collected in an Aluminum tube, one tube per box.

6.6 Instructions for use and handling

Apply to the eyelids, generally 3 times a day.

7. MARKETING AUTHORISATION HOLDER

SHANGHAI GENERAL PAHRMACEUTICAL CO., LTD

8.NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

055907/07847/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 03-05-2021

10. DATE OF REVISION OF THE TEXT

20/12/2022