SUMMARY OF PRODUCT CHARACTERSTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

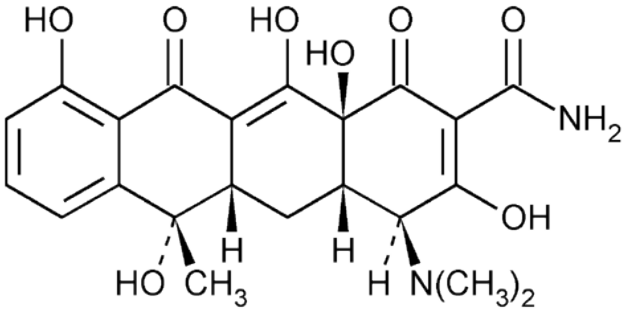
Name of product:Tetracycline Eye Ointment.

Strength: 1%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient: Tetracycline

Tetracycline



$C_{22}H_{24}N_2O_8$ 444.43
2-Naphthacenecarboxamide,
4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-met

hyl- 1,11-dioxo-, [4*S*-(4α,4aα,5aα,6β,12aα)]-.

(4*S*,4a*S*,5a*S*,12a*S*)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide [*60-54-8*].

Trihydrate 498.49 [*6416-04-2*].

3. PHARMACEUTICAL FORM

Eye Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tetracycline belongs to the family of medicines called antibiotics. Tetracycline ointment preparations are used to treat infections of the eye external use only. Tetracycline eye ointment is indicated in the treatment of conjunctivitis, trachoma and other eye infections.

4.2 Posology and method of administration

Usual adult dose: Apply the eye ointment to the lower eyelid pouch, generally 2-3 times a day.

4.3 Contraindications

This product is contraindicated in persons who have shown hyper-sensitivity to any of the tetracyclines.

4.4 Special warnings and special precautions for use

Tetracycline-class antibiotics can cause fetal harm when administered to a pregnant woman. If any tetracycline is used during pregnancy, or if the patient becomes pregnant while taking these drugs, the patient should be apprised of the potential hazard to the fetus.

The use of drugs of the tetracycline class during tooth development(last half of pregnancy, infancy and childhood to age of 8 years) may cause permanent discoloration of the teeth(yellowish-gray-brown).

This adverse reaction is more common during long- term use of the drugs but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Tetracycline drugs, therefore, should not be used druing tooth development unless other drugs are not likely to be effective or are coontraindicatied.

Precaution: After application this medicine usually causes vision to blur for a few minutes. If symptoms do not improve within a few days, or if they become worse, check with the doctor.

4.5 Interaction with other FPPs and other forms of interaction

If it is used with other drugs at the same time, drug interactions may occur. Please consult your physician or pharmacist for details..

4.6 Pregnancy and lactation

Kindly refer to Warnings.

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

Rarely happen.

4.9 Overdose

In case of overdose, treat symptomatically and institute sup-portive measures.

5. PHARMACOLOGICAL PROPERTIES

This product is a broad – spectrum antimicrobial agent, it effects at high concentration. Many rickettsia genus, mycoplasma, chlamydia genus, treponema sensitive to this product.Enterococcus is esistance to it. The product has some antibacterial activity with neissereiagonorrhoeae, ut penicillin-resistant Neisseria gonorrhoeae are resistant to tetracycline. Over the years since the widely used tetracycline, clinical common pathogens is seriously resistant to tetracycline, such as staphylococcus aureus and other gram-positive bacteria as well as enterobacteriaceae. It also has serious cross-resistance with the other species of the tetracycline class of goods. It effects by combination with bacterial 30S ribosomal subunit of A, inhibit the growth of peptide chain and impact of bacterial protein synthesis

This product is for topical use only, very little absorption.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
Paraffin
White Soft Paraffin

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 Pharmaceutical Co., Ltd

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

06122/07996/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 07-07-2021

10. DATE OF REVISION OF THE TEXT

12/12/2022