

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Tetracycline Skin Ointment, 3%, 15g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

For product Tetracycline hydrochloride Ointment, it contains 0.45g Tetracycline hydrochloride per tube.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Treatment of bacterial conjunctivitis
- Treatment of trachoma (by preference use oral azithromycin for this indication)
- Prevention of neonatal conjunctivitis

4.2 Character

This product is yellow ointment.

4.3 Action category

- Antibacterial

4.4 Specifications

3%.

4.5 Usage and dosage

First wash the affected area with warm boiled water, and then apply the ointment to the affected area 1-3 times a day.

Consult your pharmacist or physician.

4.6 Side effects

Rare.

4.7 Taboo

Tetracycline allergy is prohibited.

4.8 Matters needing attention

It is not clear.

4.9 Medication for pregnant and lactating women

It is not clear.

4.10 Drug interactions

It is not clear.

4.11 Drug overdose

It is not clear.

4.12 Term of validity

Tentative 36 months.

5 Pharmacological action

5.1 Pharmacology and Toxicology

This product is a broad-spectrum bacteriostatic with bactericidal effect at high concentration. Many Rickettsia, mycoplasma, chlamydia and spirochetes are sensitive to this product, and Enterococcus is resistant to it. For many years, because of the wide application of tetracyclines, the common clinical pathogens are resistant to tetracycline seriously, Staphylococcus and other Gram-positive bacteria and most Enterobacteriaceae bacteria are resistant. There is cross resistance between this product and different tetracycline varieties. The mechanism of action of the product is that the drug can specifically bind to the a position of 30S subunit of bacterial ribosome, inhibit the growth of peptide chain and affect the synthesis of bacterial protein.

5.2 Pharmacokinetics

No information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name
Tetracycline hydrochloride
Liquid Paraffin
White Petrolatum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30 °C. Sealed well and protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

It is sealed Aluminium tube with a cap, and kept cream inside. One Aluminium tube in one box.

6.6 Instructions for use and handling

For local external use, apply appropriate amount of this product to the affected area, once or twice a day. Ask your pharmacist how to dispose of medicines no longer required.

7. MARKETING AUTHORISATION HOLDER

Jiangxi Xier Kangtai Pharmaceutical Co.,Ltd

North Zone, High New-Tech Industrial Zone, Pingxiang, China

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

07583/08775/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Aug 2, 2022

10. DATE OF REVISION OF THE TEXT

Dec.21 , 2019.