(Summary of Product Characteristics)

1. Name of the Finished Pharmaceutical Product

Racycline Eye Ointment.

2. Qualitative and Quantitative composition

Each gram contains: Tetracycline Hydrochloride BP 10mg in sterilized paraffin base and excipients provided in section 6.1.

3.0 Pharmaceutical Form

Ophthalmic Ointment.

Yellow, semi-solid, non-gritty ointment. Filled in collapsible tubes and contained in a unit box along with literature insert.

4.0 Clinical Particulars

4.1 Therapeutic Indications

Tetracycline ophthalmic ointment is used in the treatment of eye infections caused by or associated with pathogens sensitive to tetracycline therapy.

4.2 Dosage and administration

Racycline or Tetracycline 1% Ophthalmic Ointment**:**

The ophthalmic ointment is applied to the affected eye 3 to 4 times daily or as directed by the physician.

4.3 Contraindications

Hypersensitivity to the active substance, or to any of the excipients listed in section 6.1. The tetracyclines are also contra-indicated in patients hypersensitive to any of this group of antibacterials, since cross-sensitivity may occur. They are doxycycline, methacycline, monocycline, oxytetracycline. They should be avoided in patients with systemic lupus erythematosus. Severe infections may also require concurent oral therapy for trachoma. Patients who may be exposed to direct sunlight should be warned of the risk of photosensitivity.

4.4 Precautions, Warnings and Undesirable Effects.

Racycline or tetracycline 1% Ophthalmic Ointment is contraindicated in patients with a known history of hypersensitivity to tetracyclines.

4.5 Interaction with other medicinal products and other forms of interaction

Don't use make up with retinoids when tetracyclines are applied. Ocular inflammation has occurred following the use ocular preparations preserved with thiomersal in some patients using tetracyclines. Because of possible antagonism of the action of penicillins by predominantly bacteriostatic tetracyclines it has been recommended that the two types of drugs should not be used together, especially when a rapid bactericidal action is necessary.

4.6 Pregnancy, breast-feeding and fertility

Tetracycline ophthalmic preparations have not been shown to cause birth defects or other problems in nursing babies.

4.7 Effects on Ability to Drive and Use Machines

As with all products for ocular use, transient blurring of or other disturbances may affect the ability to drive and use machines. You should wait until your clears, before you start operating machines or driving.

4.8 Undesirable effects.

Blurred vision after administration is expected. If no improvement within a few days the doctor advice is needed. Tetracycline topical ophthalmic ointment has no systematic action; in rare cases it may cause irritation of the mucosa.

Candidiasis, conjunctivitis is possible mainly due to overgrowth with Candida albicans, and there may be overgrowth of

resistant coliform organisms, such as Pseudomonas spp. and Proteus spp. Tetracycline has an anti-anabolic effects on eye mucosa.

Hypersensitivity to the tetracyclines is much less common than to the beta- lactams antibiotics. Hypersensitivity reactions, including rashes, fixed drug eruptions, exfoliative dermatitis are rare possible as the drug usage is not prolonged. Myopia in patients taking tetracyclines may be due to transient hydration of the lens.

The cases of increased muscle weakness in patients with myasthenia gravis and provocation of lupus erythematosus are reported when tetracycline applied for a long time (trachoma).

4.9 Overdose and treatment

Allergic reactions are rare and may be manifested by cutaneous lesions, local edema. Topical products that contain propylene glycol may cause skin irritation.

5.0 Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: Antibiotics; **ATC Code**: S01AA09.

Tetracycline is a bacteriostatic antibiotic with a broad-spectrum of antimicrobial activity including chlamydiae, mycoplasma, rickettsia, and spirochaetes and also many aerobic and anaerobic Gram-positive and Gram-negative pathogenic bacteria and some protozoa.

5.2 Pharmacokinetic Properties

Spectrum of activity

The tetracyclines are mainly bacteriostatic, with a broad spectrum of antimicrobial activity. The following Gram-positive and Gram-negative pathogenic bacteria are usually sensitive to tetracyclines: Staphylococcus aureus, Streptococcus pneumoniae, Listeria spp., Bacillus anthracis, Clostridium spp., Actinomyces israelii; Haemophilus influenzae, Haemophilus ducreyi, Bordetella pertussis, enterobacteria (Escherichia coli, Enterobacter spp., Enterobacter aerogenes, Klebsiella spp., Salmonella spp., Shigella spp., Yersinia pestis, Bartonella bacilliformis, Vibrio cholerae, Vibrio fetus, Rickettsia spp., Borrelia burgdorferi, Brucella spp.

Mechanism of action

Tetracyclines are taken up into sensitive bacterial cells by an active transport process. Once appeared within the cell, they reversibly affiliate to the 30S subunit of the ribosome in bacterial cells. Consequently, they prevent the binding of aminoacyl transfer RNA and inhibit the protein synthesis and hence cell growth of. The synthesis of proteins in mammalian cells is also inhibited although tetracyclines. That is why tetracyclines are not actively taken up by bacterial cells, thereby they permit the selective activity against the infecting organisms.

5.3 Preclinical Safety Data

Not applicable.

6.0 Pharmaceutical Particulars

List of Excipients

White soft Paraffin, Cetostearyl Alcohol, Liquid Paraffin, Hard Paraffin, Isopropyl Alcohol and anhydrous sodium sulphate.

6.1 Incompatibilities.

None.

6.2 Shelf Life

36 Months.

6.3 Special Precautions for Storage

Store in a dry place, below 30°C. Protect from light.

Keep all medicines out of reach of children.

6.4 Nature and Contents of Container

Yellow semi-solid, non-gritty ointment, packed in 3.5gm collapsible tubes and contained in a unit box with literature insert.

6.5 Special precaution for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7.0 Marketing Authorization Holder and Manufacturing Site

Marketing Authorization Holder:
Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
Country: Kenya
Telephone: +254 20 8040306
Telefax: +254 20 8040309
E-Mail: info@laballied.com.

8.0 Manufacturing Site Address:

LABORATORY & ALLIED LTD
Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
Country: Kenya
Telephone: +254 20 8040306
Telefax: +254 20 8040309
E-Mail: info@laballied.com

9.0 Date of first Registration/ Renewal of the Registration

Marketing Authorization Number: H95/172
First registration date: 15/12/94
Renewal: Retained annually.

10.0 Date of revision of the text:

March 2023.