Summary of Product Characteristics for Pharmaceutical Products

1. Name of the finished pharmaceutical product

Racycline Skin Ointment.

Strength:

Tetracycline Hydrochloride 3%w/w.

Pharmaceutical Form:

Ointment for topical use.

2. Qualitative and quantitative composition

The ointment contains: Tetracycline Hydrochloride BP 3%w/w.

Full list of excipients is provided in section 6.1

3. Pharmaceutical form

Ointment for topical use.

Yellow, semi-solid, non-gritty ointment. Packed in 15gm collapsible tubes and contained in a unit box with literature insert.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Tetracycline is a bacteriostatic antibiotic with a wide spectrum of activity and has been used in the treatment of skin infections caused by susceptible organisms. It is used in the topical treatment of acne and rosacea.

Tetracycline may be of benefit in the treatment of melioidosis and infected animal bites.

4.2 Posology and method of administration:

Tetracycline 3%w/w Skin Ointment: Apply the skin ointment thinly to the affected parts 2 or 3 times daily or as directed by physician.

4.3 Contraindications:

- Hypersensitivity to the active substance, any of the tetracyclines or to any of the excipients listed in section 6.1.
- Chronic renal/hepatic dysfunction;
- Renal impairment, particularly if severe;
- Systemic lupus erythematosus;
- Children under 12 years.
- Pregnancy and breastfeeding women.
- Benign intracranial hypertension has been reported following the concomitant use of tetracyclines and Vitamin A or retinoid and therefore concurrent use should be contraindicated.

4.4 Special warnings and precautions for use:

For external use only.

Avoid contact with broken or inflamed skin.

Instruct patients not to smoke or go near naked flames risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been

in contact with this product burns more easily and is a serious fire hazard.
Washing clothing and bedding may reduce product build up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction:
The absorption of tetracyclines in the gastrointestinal tract is reduced by divalent and trivalent cations such as aluminium, bismuth, calcium, iron, magnesium and zinc, and therefore concomitant administration of tetracyclines with antacids, iron preparations, milk and dairy products, or other preparations containing such cations, whether as active ingredients or excipients, is not recommended as this may result in sub therapeutic serum concentrations of the antibacterial agent. Do not use this ointment concomitantly with other skin preparations.

4.6 Fertility, Pregnancy and Lactation:
Fertility
There is no evidence on tetracycline affecting fertility.
Pregnancy
Not to be used in pregnancy unless essential to the patient's welfare. Tetracyclines cross the placenta and may have toxic effects on foetal tissues, particularly on skeletal development,
If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be appraised of the potential hazard to the foetus
Lactation
Tetracyclines are also excreted in breast milk and therefore contraindicated in nursing mothers.

4.7 Effects on ability to drive and use machines:
None Known.

4.8 Undesirable effects:
Tetracyclines appear to have a low order of toxicity and a low index of sensitization when applied topically to the skin. Dermatitis and associated symptomatology have been reported rarely with topical application.
Areas of skin treated with topical preparations containing tetracyclines will fluoresce under ultraviolet light, and patients should be advised that this effect occurs.
Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the relevant National RegulatoryAuthority.

4.9 Overdose:
There is no specific antidote available. In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Dermatologicals, antibiotics and chemotherapeutics for dermatological use, antibiotics for topical use, Tetracycline and derivatives.
ATC Code: D06AA04.

Mechanism of action

Tetracycline passively diffuses through porin channels in the bacterial membrane and reversibly binds to the 30S ribosomal subunit, preventing binding of tRNA to the mRNA-ribosome complex, and thus interfering with protein synthesis.

Pharmacodynamics

Tetracycline is a short-acting antibiotic that inhibits bacterial growth by inhibiting translation. It binds to the 30S ribosomal subunit and prevents the amino-acyl tRNA from binding to the A site of the ribosome. It also binds to some extent to the 50S ribosomal subunit. This binding is reversible in nature. Additionally, tetracycline may alter the cytoplasmic membrane of bacteria causing leakage of intracellular contents, such as nucleotides, from the cell.

5.2 Pharmacokinetic properties:

Absorption

Bioavailability is less than 40% when administered via intramuscular injection, 100% intravenously, and 60-80% orally (fasting adults). Food and/or milk reduce GI absorption of oral preparations of tetracycline by 50% or more.

5.3 Preclinical safety data:

There is no pre-clinical data of relevance to a prescriber as additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

- Hard Paraffin Wax
- Liquid Paraffin
- White Soft Paraffin

6.2 Incompatibilities:

None Known.

6.3 Shelf life:

36 Months from manufacture date.

6.4 Special precautions for storage:

Store in a dry place below 30℃.
Protect from light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container:

Yellow, semi-solid, non-gritty ointment. Packed in 15gm collapsible tubes and contained in a unit box with literature insert.

6.6 Special precautions for disposal and other handling:

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

6.7 Distribution Category:
Prescription Only Medicine (POM)

7. Marketing authorization holder
Laboratory & Allied Limited.
Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi - Kenya.

8. Marketing authorization number:

255

9. Date of first registration/ renewal of the registration:

19/02/2026

10. Date of revision of the text:

19/02/2026