Summary of Product Characteristics

1. Name of the medicinal product:

TRI ORAGIEN GEL (Tannic Acid, Choline Salicylate, Cetrimide and Lidocaine Hydrochloride Gel)

2. Qualitative and quantitative composition

Each mL contains:
Tannic Acid USP.....5 % w/v
Choline Salicylate Solution BP
Eq. to Choline Salicylate.....8 % w/v
Cetrimide BP.....0.01 % w/v
Lidocaine Hydrochloride BP.....2 % w/v

For a list of excipients, see Section 6.1.

3. Pharmaceutical form

Topical Gel for oral use.

4. Clinical particulars

4.1 Therapeutic indications

TRI ORAGIEN GEL is recommended in painful mouth ulcer, aphthous ulcer, stomatitis, glossitis, gingivitis, teething pains, denture irritation. Topical application in painful mouth ulcers /apthous ulcers relieves pain and reduces inflammation, prevent the recurrence of oral thrush and provides symptomatic relief.

4.2 Posology and method of administration

Posology

Apply 2-3 drops on the affected area. Repeat 3-4 hrs or as directed by the physician.

Method of administration

Use a clean fingertip and gently apply medication over affected area or with cotton swabs for hard-to-reach areas.

4.3 Contraindications

Except for possible hypersensitivity reactions there are no contraindications to any of the ingredients.

4.4 Special warnings and precautions for use

Before using TRI ORAGIEN GEL, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

• discontinue use if allergy occurs
• geriatric patients
• hepatically impaired patients
• paediatric patients
• do not take by mouth.

Consult with your doctor before using this medicine on open wounds, dry, chapped, irritated, or sun-burned skin.

wash your hands before and after applying TRI ORAGIEN GEL.

- Clean and dry the skin area to be treated.
- do not wash the treated area after immediately applying TRI ORAGIEN GEL. Also avoid the use of other products on the treated area unless directed by your doctor.
- applying an excessive amount may result in pilling. Use a thinner layer or lesser quantity of medicine to avoid pilling.
- avoid getting this medication in your eyes or nose or mouth.

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of TRI ORAGIEN GEL may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. TRI ORAGIEN GEL may interact with the following drugs and products:

- Aspirin
- Salicylates

4.6 Pregnancy and Lactation

This medicine is not known to be harmful when used by pregnant women, provided the recommended dose is not exceeded, but it should be avoided towards the end of the pregnancy.

Seek medical advice from the physician before using any medicine during pregnancy.

This medicine may pass into breast milk in very small amounts, but is unlikely to have any

adverse effects on a nursing infant. However, as with all medicines, always check with the

physician before using this medicine if you are breastfeeding.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Ulceration at site of application if used excessively.

Reporting of Suspected Adverse Reactions

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 requested to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Treatment of poisoning is symptomatic; demulcents and diluents may be given if necessary but emesis and lavage should be avoided. Activated charcoal may be considered if the patient presents within an hour of ingestion. Corticosteroids may reduce oropharyngeal edema.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and disinfectants
ATC code: D08A
Mechanism of action
Lidocaine is a local anesthetic of the amide type that act by reversible inhibition at the nerve impulse generation and trassmission. Hence relieving pain caused by recurrent mouth ulcers,
stomatitis, glossitis and denture irritation.
Tannic Acid - a substance of herbal origin provides a soothing astringent effect when applied to inflamed mucous membranes in the mouth.
Choline salicylate is the choline salt of salicylic acid and its pharmacology is essentially that of salicylic acid. It has exhibited anti-inflammatory analgesic and antipyretic actions in animal
models, and is taken orally or is applied topically in man for the relief of pain and inflammation.
Like salicylic acid it has no antithrombotic activity and shows a low potential for production of gastrointestinal injury when given by the oral route. The pharmacological actions of choline
salicylate are thought to be primarily mediated through inhibition of prostaglandin production, although effects on lukotriene pathways, kinin release and nerve conduction have been proposed.
Cetrimide is a quaternary ammonium antiseptic. As well as having emulsifying and detergent properties, it has antibacterial activity against gram-positive organisms and to a lesser extent against some gram-negative organisms.
Glycerin is a soothing and lubricating agent that soothes away pain.

5.2 Pharmacokinetic properties

Choline salicylate is absorbed from the gut and is likely to be absorbed across mucous membranes such as all buccal mucosa. Metabolism of salicylic acid is by glycine and phenolic or acyl glucuronate conjugation with small amounts undergoing hydroxylation. The plasma half-life of salicylic acid is 2-4 hours. Both metabolites and a small amount of intact salicylic acid are excreted, mainly in the urine. Salicylic acid is

highly (80-90%) protein bound and although it has a low apparent volume of distribution of around 0.15 1/kg it is widely distributed throughout extracellular water and most tissues.
The product is intended for local action. Lidocaine hydrochloride is well-absorbed through mucous membranes and more slowly absorbed through intact skin. TRI ORAGIEN GEL, absorption through the skin is minimal, no significant levels being found in blood.

5.3 Preclinical safety data

Given its topical application, the potential toxicity of these products is very low.

6. Pharmaceutical Particulars

6.1 List of Excipients

Carmellose Sodium, Methy Hydroxy Benzoate, Propyl Hydroxy Benzoate, Flavour Peppermint 18774, Glycerin, Propylene Glycol, and purified water.

6.2 Incompatibilities

None

6.3 Shelf-Life

36 Months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light. Keep medicine out of reach of children.

6.5 Nature and Content of container

15 ml white opaque plastic bottle with nozzle. Such 1 bottle to be packed in a carton along with Pack insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing Authorization Holder

Signature Healthcare Ltd.,
Cape Business Park, Along Thika Super Highway,
P.O.Box 66172-00800, Nairobi,
Kenya

8. Marketing Authorization Number

H2025/CTD11172/21418

9. Date of first authorization/renewal of the authorization

09/07/2023

10. Date of revision of the text

09/07/2023