SPC-Summary of Product Characteristics

1. Name of the Medicinal Product

KANALOG (Triamcinolone Acetonide Ointment USP 0.1% w/w)

2. Qualitative and Quantitative Composition

Triamcinolone Acetonide USP	0.1%w/w
Excipients	Q.S.

For Excipients see point 6.1

3. Pharmaceutical Form

Topical Ointment

4. Clinical Particulars

4.1 Therapeutic Indications

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses

4.2 Posology and Method of Administration

Topical corticosteroids are generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.

Occlusive dressing may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressing should be discontinued and appropriate antimicrobial therapy instituted

4.3 Contraindications

Hypersensitivity reactions to any component of the drug or cephalosporins, penicillins and other beta-lactam antibiotics.

4.4 Special Warnings and Precautions for use

General Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.

If irritation develops, topical corticosteroids should be discontinued and appropriatetherapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued untilthe infection has been adequately controlled.

PRECAUTIONS
Information for Patients:

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for externaluse only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder otherthan for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially underocclusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

4.5 Interactions with other medicinal products and other forms of interactions
None

4.6 Fertility, Pregnancy and Lactation

Pregnancy Category C
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on the teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Breastfeeding
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable Effects

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis,

hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects

Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anti-inflammatory, corticosteroids for systemic use

ATC code: H02AB08.

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids.

There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

5.2 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increasepercutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys.

5.3 Pre-Clinical Safety Data

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

6. Pharmaceutical Particulars

6.1 List of Excipients

Light Mineral Oil & White Petrolatum

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months from the Date of Manufacture

6.4 Special precautions for Storage

Store between temperature 20°C and 25°C. Protect from Light & heat

Do not freeze.

6.4 Nature and contents of Container

A printed carton containing a leaflet and a printed 15gm collapsible tube.

6.5 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements

5. Manufacturing Authorization Holder

Merit Organics Ltd.

Plot No 2104/2/A , G.I.D.C , Sarigam , Bhilad,

Dist Valsad-396155 Gujarat INDIA

6. Marketing Authorization Numbers

NA

7. Date of First Authorization/Renewal of Authorization

19.10.2024

8. Date of Revision of the text

Applicable once the registration is obtained