SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

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

2. Qualitative and Quantitative Composition

Each gm of Ointment contains:

Triamcinolone Acetonide USP..... 1 mg

For Excipients see point 6.1

3. Pharmaceutical Form

Topical Ointment

Physical Description: Translucent 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.

Special populations

Paediatric population

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

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.

Information for the Patient

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 Interaction with other medicinal products and other forms of interaction
None

4.6 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 pregnantwomen 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.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

ATC Classification: H02AB08**–**Antiiflammatory, corticosteroids for systemic use

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 Pharmacokinetic properties

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.
Some of the topical corticosteroids and their metabolites are also excreted into the bile.

5.3 Preclinical 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

None

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C in a dry place.

As with all medicines, keep this product out of the reach of children.Do not keep outdated medicine or medicine no longer needed.
Keep the tube in the outer carton in order to protect from light.

6.5 Nature and contents of container

1) 15 gm Aluminium Tube
2) 80 gm Aluminium Tube
3) 454 gm HDPE Container

6.6 Special Precaution for disposal

No special requirements.

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

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Marketing Authorization holder

(Company) Name: Macleods Pharmaceuticals Limited
Address: 304, Atlanta Arcade , Marol Church road, Andheri (East),
Country: India
Telephone: *+91-22-66762800*
Telefax: *+91 22-29256599*

E-Mail: export@macleodspharma,com

7.2 Manufacturer

MACLEODS PHARMACEUTICALS LTD.

At,

OXALIS LABS

Village Theda,Post office Lodhimajra,
Tehsil Baddi, District Solan,
Himachal Pradesh, IN-174101, India
Office: Atlanta Arcade, Church Road, Andheri-Kurla Road, Andheri (East)
Mumbai - 400059. INDIA.

8. Marketing Authorization Number

TAN 21 HM 0109

9. Date of first registration/ Renewal of the registration

29/03/2021

10. Date of Revision of the Text:

March 2021