SUMMARY OF PRODUCT CHARACTERISTICS

G-DERM Cream

(Betamethasone Dipropionate, Gentamicin, Tolnaftate & Iodochlorhydroxyquinoline Cream)

1. NAME OF THE MEDICINAL PRODUCT: G-DERM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each gram contains:

Betamethasone Dipropionate USP	0.643 mg
Gentamicin Sulphate B.P. equivalent to Gentamicin base	1 mg
Tolnaftate USP	10 mg
Iodochlorhydroxyquinoline	10 mg
Chlorocresol B.P. (Preservative)	1 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Topical Preparation Cream

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

G-DERM is used for relief from itching and inflammation associated with a wide variety of skin conditions like allergic dermatitis, atopic dermatitis, contact dermatitis and plaque psoriasis.

G-DERM is even indicated in topical treatment infected insect bites, minor burns, eczematoid dermatitis, seborrheic dermatitis, excoriation, lacerations, skin abscesses and cysts, skin ulcers, stasis ulcers, stings, bacterial infections of minor fungal and viral infections, sycosis barbae and minor surgical wounds

G-DERM stops the growth of fungi that causes skin infections, including athlete's foot, jock itch, ring worms, infections in nails, scalp, palms and soles. It helps in oxidative damage in Parkinson, Alzheimer, amyotrophic lateral sclerosis and other neurogenerative diseases.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Route of administration: Cutaneous

G-DERM is applied twice a day.

Thoroughly clean the infected area, allow it to dry, and then gently rub the medication on it until most of it disappears. Use just enough medication to cover the affected area. Hands should be washed after applying the medication.

Continue the treatment for at least 2 weeks after symptoms disappear. A total 4-6 weeks of treatment may be necessary.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or any of the excipients in the excipients listed in section 6.1.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Use of G-DERM occasionally allows overgrowth of non-susceptible organisms, including fungi. Large doses and prolong use of G-DERM may suppress cortisol production which may lead to increase in glucose levels.

Suppression of immune response may allow other infections to occur more easily.

Use of occlusive dressings should be avoided since higher absorption of G-DERM in the body may take place.

Pediatric population

In infants and children under 12 years of age, treatment courses should be limited to five days and occlusion should not be used; long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Application to the face

Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes; therefore, treatment courses should be limited to five days and occlusion should not be used.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure.

Concomitant infection

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

4.5 Interaction with other medicinal products and other forms of interaction

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Combining G-DERM with topical anthralin may increase psoriasis symptoms. Therefore, G-DERM should be discontinued 1 week before starting anthralin's.

Avoid using other topical preparations at the same time except under the direction of the physician

4.6. FERTILITY, PREGNANCY AND LACTATION

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

Pregnancy

There are limited data from the use of betamethasone in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development. (*see section 5.3*).

The relevance of this finding to humans has not been established; however, administration of betamethasone during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the fetus. The minimum quantity should be used for the minimum duration.

Lactation

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether topical administration of corticosteroids could result in enough systemic absorption to produce detectable amounts in breast milk. administration of betamethasone during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation betamethasone should not be applied to the breasts to avoid accidental ingestion by the infant.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

There have been no studies to investigate the effect of betamethasone on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical betamethasone.

4.8 UNDESIRABLE EFFECTS

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000) and very rare (<1/10,000), The most noted side effects of G-DERM are burning at the site of application, itching, irritation and dryness that did not usually require discontinuation of treatment. Possible photo sensitization has been reported in several patients.

4.9 OVERDOSE

Symptoms and signs

Topically applied betamethasone may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur (*see section 4.8)*.

Treatment

In the event of overdose, betamethasone should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

Further management should be as clinically indicated or as recommended by the national poisons Centre where available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Betamethasone Dipropionate in G-DERM is a topically acting corticosteroid having a potent anti-inflammatory action and acts also by suppressing the immune response.

Gentamicin in G-DERM acts as a bactericidal, actively transported across the bacterial cell membrane. DNA may be misread, thus producing nonfunctional proteins; polyribosome is split and are unable to synthesize protein.

Tolnaftate in G-DERM has antifungal activity which acts by inhibiting the growth of dermatophytes.

Iodochlorhydroxyquinoline in G-DERM provides a soothing effect by acting against secondary infections of yeast, fungi or dermatophytes.

5.2 Pharmacokinetic properties

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways like systemically administered corticosteroids. Topical corticosteroids are metabolized, primarily in the liver. Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile. Pharmacokinetic data of tolnaftate and gentamicin topical application is not available.

5.3 Preclinical safety data

Reproductive toxicity

Subcutaneous administration of betamethasone to mice or rats at doses ≥0.1 mg/kg/day or rabbits at doses ≥12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

The effect on fertility of betamethasone has not been evaluated in animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol Cetostearyl Ether (C.M. 1000), Cetostearyl alcohol, Light Liquid Paraffin, Propylene Glycol, Disodium Hydrogen Phosphate Dihydrate, Sodium Hydroxide, Purified Water.

6.2 Incompatibilities: None stated

6.3 Shelf Life: 36 Months

6.4 Special precautions for storage

Store in cool & dry place, below 30^0C.
Do not freeze.
Keep out of reach of children.
For External Use Only.
Do not swallow.

6.5 Nature and contents of container:

Printed Laminated tube with sealed nozzle with Aluminium foil & white stand up cap packed in a mono carton with leaflet.

Presentation:
15 gm /30 gm tube packed in a mono carton with a leaflet.

6.6 Special precautions for disposal

Unused G-DERM Cream should be returned to pharmacist so they can be disposed of safely.

7. MARKETING AUTHORISATION HOLDER

Greenlife Pharmaceuticals Limited,

No. 35a, Association Avenue, Ilupeju,

Lagos, Nigeria