1. NAME OF THE MEDICINAL PRODUCT

SHALIDERM CREAM (Beclomethasone Dipropionate, Clotrimazole, Gentamicin Sulphate & Tolnaftate Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Beclomethasone Dipropionate BP…….0.025 % w/w

Clotrimazole BP……1.0 % w/w

Gentamicin Sulphate BP

Eq. to Gentamicin….....0.1 % w/w

Tolnaftate USP…….....1.0 % w/w

Cream base…….……Q.S.

3. PHARMACEUTICAL FORM

Topical Cream

White coloured homogenous cream.

4. Clinical particulars

4.1 Therapeutic indications

Shaliderm is used for the treatment, control, prevention & improvement of the following diseases, conditions and symptoms:

- Folliculitis
- Furunculosis
- Paronychia
- Minor bacterial skin infections
- Candidiasis
- Tinea versicolor
- Corticosteroid-responsive dermatoses
- Fungal infections

4.2 Posology and method of administration

Posology

Adults and children over the age of 12 years.

Paediatric population

SHALIDERM CREAM is not recommended for children under the age of twelve years.

Method of administration:

Creams are especially appropriate for moist or weeping surfaces.

Apply the cream on the affected area 2-4 times daily; depending on the severity of the condition. Treatment should not be continued for more than seven days without medical supervision. If the condition worsens or does not improve within seven days, treatment and diagnosis should be re-evaluated.

Do not apply more often or use longer than prescribed. This may increase the risk of side effects. Use this medication regularly to get the most benefit from it. To help you remember, use it at the same times each day.

Continue to use this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

4.3 Contraindications

Shaliderm is contraindicated in individuals with a known hypersensitivity to any of the active ingredients or to any of the excipients listed in this product.

Shaliderm is also contraindicated in children under 12 years of age.

4.4 Special warnings and precautions for use

Before using Shaliderm, 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.

- avoid contact with the eyes
- avoid sources of infection or re-infection
- avoid wearing plastic pants or tight-fitting diapers on a child being treated in the diaper area
- do not bandage, cover or wrap the treated skin area
- 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 Shaliderm. Clean and dry the skin area to be treated.
- do not wash the treated area after immediately applying Shaliderm. 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.
- Visual disturbance has been reported by patients using systemic and/or topical corticosteroids.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity

from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is less likely to occur with topically applied Shaliderm. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further

Use in children

In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.
In children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur.

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 Shaliderm may change. Shaliderm may interact with the following drugs and products:

- Amphotericin B
- Flucytosine
- Nystatin
- Ritonavir
- Itraconazole

4.6 Fertility, pregnancy and lactation

Pregnancy:

This medicine should not be used during pregnancy unless considered essential by your doctor. If it is prescribed by your doctor it should not be used on large areas of skin, underneath airtight dressings, or for prolonged periods of time. Consult your doctor for further information.

Lactation:

This medicine should not be used during breastfeeding unless considered essential by your doctor. If it is prescribed by your doctor it should not be used on large areas of skin, underneath airtight dressings or for prolonged periods of time. If it is applied to the breasts it should be washed off carefully before breastfeeding and then reapplied afterwards.

Fertility:

There are no data in humans to evaluate the effect of Shaliderm cream on fertility.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of Shaliderm cream on driving performance or the ability to operate machinery.

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), very rare (<1/10,000 including isolated reports) and Not Known (cannot be estimated from the available data).

Infections and Infestations	
Very rare	Opportunistic infection
Immune System Disorders	
Very Rare	Local hypersensitivity
Not Known	Anaphylactic reaction
Endocrine Disorders	
	Very rare Hypothalamic-pituitary adrenal (HPA) axis suppression (see also Skin and Subcutaneous Tissue Disorders): Cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels
Skin and Subcutaneous Tissue Disorders	
Common	Pruritus, local skin burning/pain of skin
Uncommon	Skin inflammation
Very rare	Allergic contact dermatitis/dermatitis, erythema, rash, urticaria, pustular psoriasis, skin thinning*/ skin atrophy*, skin wrinkling*, skin dryness*, striae*,telangiectasias*, pigmentation changes*, hypertrichosis, exacerbation of underlying symptoms, alopecia*, trichorrhexis*
Not Known	Angioedema
General Disorders and Administration Site Conditions	
Uncommon	Application site reactions (including application site irritation, burning, pruritus, reaction NOS and warmth)
Very Rare	Pain

**Skin features of hypothalamic-pituitary adrenal (HPA) axis suppression*

4.9 Overdose

Symptoms and signs

Topically applied beclomethasone dipropionate and gentamicin sulphate 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.

Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy. In case of accidental ingestion, stomach irritation may occur.

Treatment

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

Consideration should be given to significant systemic absorption of gentamicin sulphate. If this is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and Blood levels of gentamicin sulphate should also be determined.

Haemodialysis may reduce the serum level of gentamicin sulphate.

Shaliderm cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory, Antibiotic & Antifungal

ATC code:

Beclometasone Dipropionate: D07AC01,

Gentamicin Sulphate: D06AX07,

Clotrimazole: D01AC01,

Tolnaftate: D01AE18

Mechanism of action:

Beclometasone Dipropionate is a steroid medicine. It blocks the production of certain chemical messengers (prostaglandins) that make the skin red, swollen and itchy.

Gentamicin is an antibiotic which kills bacteria by preventing synthesis of essential proteins required by bacteria to carry out vital functions.

Clotrimazole works as an antifungal that helps in stopping the increasing growth of fungi. It also works in preventing the fungi from forming their own protective layer.

Tolnaftate has fungicidal properties, is a thiocarbamate derivative that inhibits sterol synthesis at

the level of squalene epoxidase in the growing cells.

5.2 Pharmacokinetic properties

Beclometasone Dipropionate:

Absorption

Topical corticosteroids can be systematically 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.

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Distribution

87% protein bound (94% to 96% for Beclometasone Dipropionate).

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Gentamicin Sulphate:

Absorption

Topical application of gentamicin has been reported to occur from wounds and inflamed skin. It is poorly absorbed from the gastrointestinal tract when administered orally.

Distribution

Absorbed gentamicin distributes to tissues. Aminoglycosides appear to accumulate in body tissues to some extent, mainly in the kidney.

Metabolism and Elimination

The plasma elimination half-life for gentamicin has been reported to be 2 to 3 hours though it may be considerably longer in neonates and patients with renal impairment. Gentamicin and des do not appear to be metabolised and are excreted virtually unchanged in the urine by glomerular filtration.

Clotrimazole:

Absorption

There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.

Distribution

Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6 %).

Metabolism and Elimination

The small amount of miconazole that absorbed is absorbed is eliminated predominately in faeces as both unchanged drug and metabolities.

Tolnaftate:

Absorption

Absorption through intact skin is minimal.

Distribution

Distribution after topical administration is primarily local.

Metabolism and Excretion

Systemic metabolism and excretion not known following local application.

5.3 Preclinical safety data

Non-clinical studies have not been conducted with the combination of Beclomethasone Dipropionate, Clotrimazole, Gentamicin Sulphate & Tolnaftate Cream.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft Paraffin, Light Liquid Paraffin, Cetostearyl Alcohol, Cetomacrogol 1000, Methyl Paraben, Propyl Paraben, Propylene Glycol, Disodium Edetate, Disodium hydrogen orthophosphate, Para Chloro meta cresol, Sodium dihydrogen orthophosphate, Perfume Fragrance & Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C in a dry place. Do not freeze. Protect from light.

6.5 Nature and contents of container

SHALIDERM CREAM is a white coloured homogenous cream filled in a 30 gm printed lami tube packed in a printed carton along with leaflet.

6.6 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

GENEITH PHARM LTD.

12 Adewale Crescent, Off Ewenla Street,

Off Oshodi, Apapa,

Lagos, Nigeria

8. Marketing authorisation number(s)

BD/29

9. Date of first authorisation/renewal of the authorisation

01/01/2023

10. Date of revision of the text

29/12/2027