SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product:
Dermocort Cream (Clobetasol Propionate & Neomycin Sulphate Cream)

2. Qualitative and Quantitative composition:

No.	Ingredients	Specification	Quantity in gm /Tube	Reason for inclusion
ACTIVE				
1.	Clotrimazole	USP	0.150	Active
2.	Bebamethasone	USP	0.0375	Active
3.	Neomycin Sulphate	USP	0.125	Active
	Preservative Chlorocresol	USP	0.130	Active
INACTIVE				
3.	Benzyl Alcohol	BP	0.15	Preservative
4.	Cetostearyl Alcohol	BP	1.08	Emulsifier
5.	Glycerin	BP	1.125	Humectants
6.	Cetomacrogol 1000	BP	0.27	Emulsifier
7.	Light Liquid Paraffin	BP	0.75	Emollient
8.	Propylene Glycol	BP	1.5	Solvent
9.	Disodium Hydrogen Phosphate Dihydrate	BP	0.0045	Buffer
10.	Purified Water	BP	q.s. to 15 gm	Solvent

3. Pharmaceutical Form: Cream

4. Clinical Particulars:

4.1 Therapeutic Indications:

Local therapy for mycotic infections eg, tinea manum, tinea corporis, tinea inguinalis, etc.

4.2 Posology and method of administration:

Apply externally to the affected area 2 times a day.

Ordinary tinea corporis, inguinalis: 2 weeks; **tinea pedis, tinea manum:** 4 weeks.

For topical administration.

4.3 Contraindications

Long-term treatment of ulcerative conditions, rosacea, pruritus, presence of acute infections. Hypersensitivity, Burning, Stinging, Itching, Skin atrophy, Irritation, Dryness, Hypopigmentation, Acneiform eruptions, Cracking and fissuring of the skin

4.4 Special warnings and precautions for use

Long term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur readily even without occlusion.

If used in childhood, or on the face, courses should be limited to 5 days and occlusion should not be used. It should be noted that the child's napkin may act as an occlusive dressing.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If the cream does enter the eye, it should be bathed in copious amounts of water.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses, development of tolerance, risk of generalized pustular psoriasis and development of local or systemic toxicity due to impaired barrier

function of the skin. If used in psoriasis careful patient supervision is important.Extension of the infection may occur due to the masking effect of the steroid.

If infection persists, systemic chemotherapy is required. Any spread of infection requires withdrawal of topical corticosteroid therapy.

Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings and the skin should be cleansed before a fresh dressing is applied.

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; and neomycin has nephrotoxic potential.

In renal impairment, the plasma clearance of neomycin is reduced .Extended or recurrent application may increase the risk of contact sensitization.

Products which contain antimicrobial agents should not be diluted.

4.5 Drug Interaction:
Neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents following significant systemic absorption. However, if used in accordance with the recommendations systemic exposure to neomycin sulphate is expected to be minimal and drug interactions are unlikely to be significant. No hazardous interactions have been reported with use of clobetasol propionate. No studies have been performed with Ketoconazole.

4.6 Pregnancy and Lactation:
There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus the use of Clobetasol/neomycin Cream is not recommended in pregnancy and lactation.
There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole.

The safe use of clobetasol propionate during lactation has not been established.

4.7 Effects on the ability to drive and use machines
Not applicable.

4.8 Undesirable effects:
Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria,local skin burning and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the conditions under treatment.

As with other topical corticosteroids prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercortisolism. This effect is more likely to occur in infants and children and if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing. Provided the weekly dosage is less than 50g
in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased.The same applies to children given a proportionate dosage.

Prolonged and intensive treatment with a highly active corticosteroid preparation may cause local atrophic changes in the skin such as thinning,striae, and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.
In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal)
is thought to have provoked the pustular form of the disease There are reports of pigmentation changes and hypertrichosis with topical steroids.If signs of hypersensitivity appear, application should be stopped immediately.
Exacerbation of symptoms may occur.

4.9 Overdose:

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually under medical supervision because of the risk of adrenal insufficiency.

Also, consideration should be given to significant systemic absorption of neomycin sulphate If this is suspected, use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

Blood levels of neomycin sulphate should also be determined. Haemodialysis may reduce the serum level of neomycin sulphate.

Excessive topical application of Ketoconazole may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.

Ingestion

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, Antibacterial

(i) ATC code: Clobetasol Propionate :D07AD01

(ii) ATC code : Neomycin Sulphate : D06AX04

(iii) ATC code : Ketoconazole : D01AC08

Ketoconazole is a broad-spectrum antifungal agent. It affects the cell membrane by changing its permeability. It shows potent antifungal action against many kinds of dermophytes (eg, trichophyton, microsprorum, epidermophyton, etc), saccharomyces, *Candida albicans* and other non-resistant organisms.

Clobetasol Propionate is a highly active corticosteroid. Corticosteroids are medicines used for reducing inflammation. Inflammation of the skin happens due to irritation of the skin, and is caused by the release of various substances that are important in the immune system. These substances cause blood vessels to widen and result in the irritated area becoming red, swollen, itchy and painful, such as is seen in dermatitis or eczema.
When Clobetasol is applied to the skin it works by acting inside the skin cells to decrease the release of these inflammatory substances. This reduces swelling, redness and itch.

Neomycin is an antibiotic of the aminoglycoside type and is used to treat infections with bacteria. It works by affecting the bacteria's production of certain proteins that are necessary for their survival. It causes the bacteria to produce abnormal and faulty proteins. This ultimately kills the bacteria. Neomycin is included in this preparation to treat the bacteria that sometimes infect inflammatory skin diseases.

Actively transported across the bacterial cell membrane, binds to a specific receptor protein on the 30 S subunit of bacterial ribosomes, and interferes with an initiation complex between mRNA (messenger RNA) and the 30 S subunit, inhibiting protein synthesis. DNA may be misread, thus producing nonfunctional proteins; polyribosomes are split apart and are unable to synthesize protein.

5.2 Pharmacokinetic properties

Ketoconazole :

After a single topical application to the chest, back and arms of normal volunteers, systemic absorption of ketoconazole was not detected at the 5 ng/ml level in blood over a 72-hour period.

Clobetasol Propionate:

Absorption:

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. Mean peak plasma Clobetasol propionate concentrations of 0.63ng/mL occurred in one study eight hours after the second application (13 hours after an initial application) of 30g clobetasol propionate 0.05% ointment to normal individuals with healthy skin. Following the application of a second dose of 30g clobetasol propionate cream 0.05% mean peak plasma concentrations were slightly higher than the ointment and occurred 10 hours after application. In a separate study, mean peak plasma concentrations of approximately 2.3ng/mL and 4.6ng/mL occurred respectively in patients with psoriasis and eczema three hours after single application of 25g clobetasol propionate 0.05% ointment.

Distribution:

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.

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 Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

Neomycin Sulfate

Absorption**:**

Although not absorbed through intact skin, topical neomycin is readily absorbed from large denuded, burned, or granulating areas. Greater and more rapid absorption occurs with neomycin cream than with the ointment.

5.3 Pre-clinical Safety:

There are no preclinical data of relevance to the prescriber which are in addition to that in other sections of the SmPC.

6. Pharmaceutical Particulars:

List of Excipients:

Clotrimazole	BP
Betamethazone	BP
Neomycin Sulphate	BP
Preservative Chlorocresol	BP
Cream base	BP
Propylene Glycol	BP

Disodium Hydrogen Phosphate Dihydrate	BP
Purified Water	BP

6.2 Incompatibilities: None are known

6.3 Shelf Life: 24 months.

6.4 Special Precautions for storage:
Store below 30°C, protect from light .Do not freeze.

6.5 Nature and contents of container:
Lami tube containing 15 g cream is packed in a primary carton along with the Pack Insert.

6.6 Special precautions for disposal and other handling:
No special requirements.

7. Marketing Authorization Holder:
Grace Drugs & Healthcare Ltd., 1A, Ogunlana Drive, Surulere, Lagos.

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text:
June 2021