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CUSTOMER : IDAMAN PHARMA MANUFACTURING SDN BHD
DESCRIPTION : Dermal G Cream
MEASUREMENT : W:100mm X H:145mm
MATERIAL : SMPO 060
COLOUR : BLACK
FINISHING : FOLD
MATERIAL CODE: Lt-402.00
Attn : MS ZAKIAH
From : MALA
I hereby verify & confirm that this draft is the final copy. Any subsequence changes of the design and content of the end product will not be borne by THUNDER PRINT SDN. BHD.
Customer Signature & Date
8.3.2024

145mm

pharmaniaga™

Dermal G
Cream

Betamethasone DP with Gentamicin

DESCRIPTION
White, smooth textured cream.

COMPOSITIONS
Each gram contains Betamethasone (as dipropionate) 0.05% w/w and Gentamicin (as sulphate) 0.10% w/w.

Also contains chlorocresol as preservative.

ACTIONS
Betamethasone dipropionate is a highly potent corticosteroid with local anti-inflammatory action.

Gentamicin is an aminoglycoside antibiotic with bactericidal action against many strains of Gram-negative bacteria including Pseudomonas, and some strains of Gram-positive microorganisms, including *Staphylococcus aureus.* Anaerobic organisms, yeast and fungi are resistant to gentamicin.

Betamethasone dipropionate can undergo systemic absorption across the stratum corneum. Once absorbed it enters pharmacokinetic pathways similar to systemically administered corticosteroids. Repeated application results in a cumulative depot effect in the skin, which may lead to a prolonged duration of action, increased side-effects and increased systemic absorption.

Although not absorbed through intact skin, topical gentamicin is readily absorbed from large denuded, burned or granulating areas.

INDICATIONS
For short-term treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses when bacterial infection is suspected.

CONTRAINDICATIONS
Hypersensitivity to corticosteroids, gentamicin or propylene glycol.

Corticosteroid preparations are contraindicated in the treatment of herpes simplex, vaccinia or varicella, or tuberculous infections of the anal region (chronic fissure).

Use is also contraindicated in infants below 1 year.

ADVERSE REACTIONS
Corticosteroids may cause allergic contact dermatitis, folliculitis, furunculosis, pustules, pyodema, hyperaesthesia, numbness in fingers, purpura, skin atrophy, acneiform eruptions and hypopigmentation.

Adverse reactions reported with gentamicin are associated with hypersensitivity reactions. Ototoxicity may be a hazard particularly in children, in the elderly and in those with renal impairment if gentamicin is applied to large areas of skin.

WARNING
Use of topical gentamicin preparation in closed hospital settings is actively discouraged. Swabs for bacteriological examinations should be taken before beginning treatment for resistant organisms.

100mm

145mm

PRECAUTIONS
When applied topically, particularly to large areas, or when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects resulting in reversible HPA axis suppression. Therefore, patients should be evaluated periodically using the urinary free-cortisol and ACTH stimulation tests.

Since gentamicin is not effective against fungi, appropriate antifungal therapy should be instituted in the presence of superficial yeast or fungus infections.

Care must be taken to maintain hygiene measures. It should also be noted that not all skin conditions that are oozing, crusted, or characterised by pustules are actually infected.

Pregnancy
There are no adequate and well-controlled studies of topical corticosteroids in pregnant women. Problems with topical gentamicin in pregnant women have not been documented. As topical corticosteroids can be absorbed systemically, it should not be used extensively or for long periods of time in pregnant women.

Breast-feeding
It is not known whether topical corticosteroids or gentamicin are distributed into breast milk. However, problems in humans have not been documented. Systemic corticosteroids are distributed into breast milk and may cause unwanted effects in the infant. Topical corticosteroids should not be applied to the breasts prior to nursing.

DRUG INTERACTION
None known.

Effects on Ability to Drive and use machine
None known.

DOSAGE AND ADMINISTRATION
Apply a thin film to the affected area once or twice daily up to a maximum of 45 g per week.

Treatment should be limited to two consecutive weeks.

OVERDOSAGE
Topically applied cream can be absorbed in sufficient amounts to produce systemic effects. Since there is no specific antidote available treatment is symptomatic supportive and consists of discontinuance.

Gradual withdrawal of the preparation may be necessary.

ROUTE OF ADMINISTRATION
Topical

STORAGE CONDITIONS
Store below 30°C.
Protect from light.
Keep container tightly closed.

SHELF LIFE
Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION
Tubes of 5 g and 15 g.

Date of Revision: 01 Mar 2024

PRODUCT REGISTRATION HOLDER:
Pharmaniaga Manufacturing Berhad (198001006232)
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi,
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Lt-402.00

100mm