Thunder Print Sdn. Bhd.(374290-X)
6463, Lorong Ayam Didik 2, Taman Ria Jaya Light Industrial Park,
08000 Sg. Petani, Kedah Darul Aman. Tel : 04-4418 005 Fax : 04-4424 005

CUSTOMER : INSPIRAPHARMA SDN BHD
DESCRIPTION : Dermal SA Ointment
MEASUREMENT : L:150mm X H:150mm
MATERIAL : SMPO 060

COLOUR : BLACK
FINISHING : FOLD

MATERIAL CODE:
Lt-413.00

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

10.2.2026

150mm

pharmaniaga™

Dermal SA

Ointment

Betamethasone DP with Salicylic acid

DESCRIPTION

A smooth clear ointment.

COMPOSITION

Each gram contains Betamethasone (as dipropionate) 0.05% w/w and Salicylic Acid 3.0% w/w.

ACTIONS

Betamethasone dipropionate is a corticosteroid, which acts by diffusing across cell membranes and complexing with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA (chromatin), and stimulate transcription of messenger RNA (mRNA) and subsequent protein synthesis of various inhibitory steroids. These anti-inflammatory effects include inhibition of early processes such as oedema, fibrin deposition, capillary dilatation, movement of phagocytes into the area, and phagocytic activities. Later processes, such as capillary production, collagen deposition, and keloid formation, are also inhibited by corticosteroids. The overall actions of topical corticosteroids are catabolic.

Salicylic acid is a keratolytic. It facilitates desquamation by solubilising the intracellular cement that binds scales in the stratum corneum, thereby loosening the keratin. This keratolytic effect may provide an antifungal action because removal of the stratum corneum suppresses fungal growth; it also aids in the penetration of other antifungal agents. Salicylic acid also has a mild antiseptic action.

Betamethasone dipropionate and salicylic acid may be absorbed systemically. The extent of absorption of topical corticosteroid is determined by many factors including the vehicle and the integrity of the epidermal barrier. Salicylic acid enhances the penetration of the corticosteroid.

INDICATIONS

Psoriasis, chronic atopic dermatitis, neurodermatitis, lichen planus, eczema, serborrhoeic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

CONTRAINDICATIONS

This product is contraindicated in patients with untreated bacterial, fungal or viral skin lesions, rosacea and perioral dermatitis and in patients who have a history of hypersensitivity to corticosteroids, salicylic acid or propylene glycol.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently when topical corticosteroids are used as recommended. These reactions are listed in 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, miliaria. Salicylic acid may cause a localised irritant reaction.

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.

In the presence of an infection, an appropriate antifungal or antibacterial agent should be used. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been controlled adequately.

Pregnancy/ Reproduction

Although studies in humans have not been done, studies in animals have shown that topical corticosteroids and salicylic acid are systemically absorbed, and may cause foetal abnormalities.

Therefore this product should not be used extensively, in large amounts or for protracted periods in pregnant patients or in patients who are planning to become pregnant.

150mm

Breast-feeding
Safety of use during lactation has not been established. However, systemic corticosteroids are excreted in breast milk and may cause unwanted effects in the infant such as growth suppression. Salicylic acid may also be systemically absorbed. Breast-feeding is not advised when using this product.

Paediatrics
Children and adolescents may demonstrate greater susceptibility to adrenal suppression. Crushing's syndrome, intracranial hypertension, and growth retardation. This is due to larger skin surface area to body-weight ratio, which results in greater amount of systemic absorption.

Young children may also be at an increased risk of toxicity because of increased absorption of salicylic acid through the skin. In addition, young children may have a lower threshold for skin irritation from salicylic acid. Salicylic acid should not be applied to large areas of the body, for prolonged periods of time, or under occlusion to substantial areas.

This product should be avoided in children below 1 year of age or if necessary, used with great care for short periods.

DOSAGE AND ADMINISTRATION
Apply thinly to the affected area once or twice daily up to a maximum of 60 g weekly.

Treatment should be discontinue when the dermatological disorder is controlled.

OVERDOSAGE
Topically ointment can be absorbed in sufficient amounts to produce systemic effects.

Symptoms of salicylism include confusion, dizziness, headache, rapid breathing, ringing or buzzing in ears.

Since there is no specific antidote available, treatment is symptomatic, supportive and consists of discontinuation of therapy. Gradual withdrawal of the preparation may be necessary.

ROUTE OF ADMINISTRATION
Topical.

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

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

PRESENTATION
Tubes of 15 g.

Date of revision: 10 Feb 2026

PRODUCT REGISTRATION HOLDER:
Pharmaniaga Manufacturing Berhad **(198001006232)**
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

MANUFACTURER:
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08000 Sungai Petani,
Kedah Darul Aman.

Lt-413.00

150mm

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