

Dervit-B Ointment

(Calcipotriol BP + Betamethasone USP)

0.005%

0.05%

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ڈروٹ-بی
کیلسیپوٹریول + بینامیتھاسون
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COMPOSITION:

Each gram of ointment contains:

Calcipotriol (as Hydrate) BP 50mcg.

Betamethasone (as Dipropionate) USP ... 0.5mg.

Mfg. Specs. NQ.

PHARMACODYNAMIC PROPERTIES:

Calcipotriol is a vitamin D analogue. In vitro data suggests that calcipotriol induces differentiation and suppresses proliferation of keratinocytes. This is the proposed basis for its effect in psoriasis. Like other topical corticosteroids, Betamethasone Dipropionate has anti-inflammatory, antipruritic, vasoconstrictive and immunosuppressive properties, however, without curing the underlying condition. Through occlusion the effect can be enhanced due to increased penetration of the stratum corneum. The incidence of adverse events will increase because of this. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear.

INDICATION: Dervit-B Ointment is indicated for the topical treatment of psoriasis.

CONTRAINDICATIONS:

Hypersensitivity to any substance of drug. Patients with known disorders of calcium metabolism and patients with severe liver and kidney disease. Due to the content of corticosteroid Dervit-B Ointment is contraindicated in the following conditions: Viral (e.g. herpes or varicella) lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis or syphilis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, ulcers, wounds, perianal and genital pruritus.

DOSAGE & ADMINISTRATION:

Dervit-B Ointment should be applied to the affected area once daily. The recommended treatment period is 4 weeks. There is experience with repeated courses of Dervit-B Ointment up to 52 weeks. If it is necessary to continue or restart treatment after 4 weeks, treatment should be continued after medical review and under regular medical supervision. When using Calcipotriol containing medicinal products, the maximum daily dose should not exceed 15g. The body surface area treated with Calcipotriol containing medicinal products should not exceed 30%.

METHOD OF ADMINISTRATION:

Dervit-B Ointment should be applied to the affected area. In order to achieve optimal effect, it is not recommended to take a shower or bath immediately after application of Dervit-B Ointment.

SPECIAL POPULATIONS:

Renal and hepatic impairment: The safety and efficacy of Dervit-B Ointment in patients with severe renal insufficiency or severe hepatic disorders have not been evaluated.

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Paediatric population: The safety and efficacy of **Dervit-B Ointment** in children below 18 years have not been established.

OVERDOSAGE:

Use above the recommended dose may cause elevated serum calcium which should rapidly subside when treatment is discontinued. Excessive prolonged use of topical corticosteroids may suppress the pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases symptomatic treatment is indicated. In case of chronic toxicity the corticosteroid treatment must be discontinued gradually.

PRECAUTION:

Dervit-B Ointment should not be used on the face. Wash your hands after each application. If used for treatment of psoriasis of the hands, avoid any contact with your face. Do not use **Dervit-B Ointment** for prolonged periods on large skin areas and under occlusive dressings, unless instructed by the doctor. If you have diabetes mellitus, inform your doctor as the steroid in **Dervit-B Ointment** may affect your blood glucose level.

Dervit-B Ointment should be used with caution in patients with severe liver and kidney disease.

PREGNANCY:

There is no adequate data for the use of **Dervit-B Ointment** (Calcipotriol/Betamethasone Dipropionate Ointment) in pregnant women. Therefore, during pregnancy, **Dervit-B Ointment** should only be used when the potential benefit justifies the potential risk.

BREASTFEEDING:

Betamethasone passes into breast milk but risk of an adverse effect on the infant seems unlikely with therapeutic doses. There are no data on the excretion of Calcipotriol in breast milk. Caution should be exercised when prescribing **Dervit-B Ointment** to women who breast feed. The patient should be instructed not to use **Dervit-B Ointment** on the breast when breast feeding.

SIDE EFFECTS:

In some patients, **Dervit-B Ointment** may cause itching which, however, is mild and transient. Consult your doctor if the itching persists. Other local reactions, reported with the use of Calcipotriol may occur and include local transient irritation, dermatitis, erythema and aggravation of psoriasis. Topical use of steroids can result in skin atrophy, telangiectasia striae, especially during prolonged application. As with other glucocorticoids, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis and depigmentation, although rare, may occur. Very rarely systemic effects after local application of the ointment may appear, such as hypercalcaemia from the Calcipotriol or inhibition of the adrenal cortex from the corticosteroid.

INSTRUCTIONS:

For external use only. Store below 30°C. Protect from heat and light. Keep out of the reach of children.

PRESENTATION: **Dervit-B Ointment** is available in pack size 30g.



Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.

صرف بیرونی استعمال کے لئے۔
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

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