

W=100 mm

Betol

Ointment

Betamethasone Dipropionate BP and Calcipotriol BP

COMPOSITION

Each gram ointment contains Betamethasone (as dipropionate) BP 0.5 mg and Calcipotriol BP 0.05 mg.

PHARMACOLOGY

Betol (Betamethasone and Calcipotriol) Ointment combines the pharmacological effects of Betamethasone dipropionate as a synthetic corticosteroid and calcipotriol hydrate as a synthetic vitamin D₃ analog. Betamethasone dipropionate has anti-inflammatory, anti-pruritic, vasoconstrictive and immunosuppressive properties. In vitro data suggests that calcipotriol induces differentiation and suppresses proliferation of keratinocytes.

INDICATION

Betol Ointment is indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION

Route of Administration: Topical preparation.

Apply an adequate layer of Betol Ointment to the affected area(s) once daily for up to 4 weeks. Betol Ointment should be rubbed gently and completely. Patient should wash their hands after applying Betol Ointment. After achieving control, therapy should be discontinued.

CONTRAINDICATION

Betamethasone and Calcipotriol containing preparation is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. It is also contraindicated in patients with known disorders of calcium metabolism. Patients with severe renal insufficiency or severe hepatic disorders are also contraindicated.

WARNING & PRECAUTION

Patients 18 years and older should not use more than 100 g per week and patients 12 to 17 years should not use more than 60 g per week. Treatment of more than 30% body surface area is not recommended. It should not be used with occlusive dressings unless directed by a physician. It should not be used on the face, groin, or axillae, or if skin atrophy is present at the treatment site. It is not for oral, ophthalmic, or intravaginal use. If irritation develops, treatment with Betol Ointment should be discontinued and appropriate therapy instituted.

SIDE EFFECTS

Common side effects: The most common side effects are itching and rash. Other common side effects are redness, irritation and burning sensation of the skin, inflamed hair pores, thinning of the skin (atrophy).

Rare side effects: Angioedema and facial oedema.

USE IN PREGNANCY AND LACTATION

Pregnancy category-C. Calcipotriol has been shown to be fetotoxic and betamethasone dipropionate has been shown to be teratogenic in animal when given systemically. There are no adequate and well controlled studies in pregnant women. Betol ointment should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. Safety of the use of Betol Ointment during lactation has not been established. It is not known whether topically administered Betol Ointment is excreted in human milk.

USE IN CHILDREN & ADOLESCENTS

Safety and effectiveness of the use of Betol Ointment in pediatric patients under the age of 12 years have not been established.

DRUG INTERACTION

No such information available.

OVER DOSE

Using too much Betol Ointment puts at risk of hypercalcemia, resulting symptoms like kidney stones, constipation, and vomiting. Long-term use could cause the body to stop making its own natural steroids.

STORAGE

Store below 30° C and dry place, protected from light.

Keep all medicines out of reach of children.

PACKING

Each box contains 20 g ointment in a tube.

*Further information is available upon request.



Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness

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