

Betameson™

Betamethasone

COMPOSITION

Betameson™ Cream: Each gram cream contains Betamethasone 0.5 mg as Betamethasone Dipropionate BP.

Betameson™ Ointment: Each gram ointment contains Betamethasone 0.5 mg as Betamethasone Dipropionate BP.

INDICATION

Betameson™ (Betamethasone Dipropionate) cream and ointment is indicated for the relief of the inflammatory and pruritic manifestations of resistant or severe corticosteroid-responsive dermatoses. These include-

- Atopic eczema
- Nummular eczema
- Contact dermatitis
- Neurodermatitis
- Anogenital and senile pruritus
- Lichen planus
- Psoriasis

DOSAGE AND ADMINISTRATION

Apply a thin film once or twice daily to cover completely the affected area. Patients with chronic psoriasis who have achieved at least a marked improvement in their psoriatic lesion (i.e., approximately 80% improvement) with Betamethasone Dipropionate may be maintained in remission with a pulse dosing regimen consisting of three consecutive applications of up to 3.5 g each of Betamethasone Dipropionate cream and ointment, twelve hours apart (e.g., morning, evening, following morning) to the previously affected areas once each week. For this purpose, Betamethasone Dipropionate cream and ointment should be applied to the lesion sites previously affected and treated. Patients on this pulse dose regimen who relapse should be reverted back to the conventional dosing regimen.

CONTRAINDICATION

Hypersensitivity to Betamethasone Dipropionate, other corticosteroids or any components in this preparation. Like other topical corticosteroids, Betamethasone Dipropionate is contraindicated in viral infections of the skin, such as vaccinia, varicella and *Herpes simplex*, also tuberculosis, acne rosacea, fungal skin infections (moniliasis), perioral dermatitis and ulcerative conditions.

PRECAUTIONS

Betamethasone Dipropionate should not be used in or near the eyes, as there is a potential risk of developing glaucoma and cataract. If irritation

or sensitisation develops with the use of Betamethasone Dipropionate, treatment should be discontinued and appropriate therapy instituted. In the presence of an infection, an appropriate antifungal or antibacterial agent should be administered. If a favourable response does not occur promptly, Betamethasone Dipropionate should be discontinued until the infection has been controlled adequately.

Corticosteroids are known to be absorbed percutaneously, therefore in patients under prolonged and extensive topical treatment, the possibility of systemic effects should be kept in mind. Betamethasone Dipropionate is not intended for use under occlusive dressings since this will also increase systemic absorption of the corticosteroid. In infants the napkin may act as an occlusive dressing and increase absorption. Suitable precautions should be taken when using topical corticosteroids in patients with stasis dermatitis and other skin diseases with impaired circulation. Prolonged use of topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued.

ADVERSE EFFECTS

The most frequent side effects reported with Betamethasone Dipropionate are mild to moderate transient burning/stinging, dry skin, pruritus, irritation and folliculitis. Rarely reported adverse effects include tingling, prickly skin/tightening or cracking of skin, warm feeling, laminar scaling and perilesional scaling, follicular rash, skin atrophy, erythema, urticaria, vesiculation, telangiectasia, acneiform papules and hyperaesthesia. Adverse reactions reported with the use of the Betamethasone Dipropionate ointment pulse dose regimen were mild intermittent hypertension and paraesthesia. Other local adverse reactions that have been reported with the use of topical corticosteroids include: itching, hypertrichosis, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae, miliaria and exacerbation of untreated infections.

STORAGE

Store below 25° C. Keep out of reach of children.

HOW SUPPLIED

Betameson™ Cream: Each pack has a laminated tube containing 20 gm cream.

Betameson™ Ointment: Each pack has a laminated tube containing 20 gm ointment.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH