Dawavate®
Betamethasone (as Valerate) BP
0.1% w/w Cream

DESCRIPTION
A white non-greasy and non- gritty Cream.
PHARMACOLOGY
Betamethasone valerate is a synthetic corticosteroid for topical dermatologic use. Betamethasone has a high degree of glucocorticoid activity and virtually no mineralocorticoid activity.
Like other topical corticosteroids, Betamethasone valerate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.
PHARMACOKINETICS
The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressing for up to 24 hours has not been demonstrated to increase penetration; however, occlusion for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.
INDICATIONS, DOSAGE AND DIRECTIONS FOR USE
For external use only.
The preparation should be applied twice daily on the affected areas.
Betamethasone valerate is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis.
In the treatment of moderate to severe plaque-type psoriasis, Betamethasone valerate applied to 5-10% of body surface area can be used up to 4 consecutive weeks. The total dosage should not exceed 50 g per week. When dosing for more than 2 weeks, any additional benefits of extending treatment should be weighed against the risk of HPA suppression. Treatment beyond 4 consecutive weeks is not recommended.
Some guidelines for the correct use of topical corticosteroids recommend that the starting of treatment should be with a more potent preparation, treatment may then be continued with a less potent preparation and with less frequent application, once control is obtained. The most potent topical corticosteroids are generally reserved for recalcitrant dermatoses. Once the skin has healed, treatment should be tailed off. Particular care is necessary in the use of topical corticosteroids in children, and the more potent preparations like Betamethasone valerate are contra-indicated in infants under 1 year of age, although potent preparations may be needed briefly in older children. It has been suggested that a 'steroid holiday' of at least 2 weeks be considered in children after each 2 or 3 weeks of daily topical therapy to allow thinned epidermis to restore itself and maintain its barrier function.
Care is also necessary in applying corticosteroids to certain anatomical sites such as the face and flexures; some advocate using only hydrocortisone 0.5 or 1% on the face. Advice should be given that topical corticosteroids should be applied sparingly in thin layers, by smoothing gently into the skin preferably after a bath, and that no benefit is gained from more frequent than twice daily application or by vigorous rubbing.
CONTRA-INDICATIONS
The preparation is contraindicated in those patients with a history of hypersensitivity to corticosteroids.
SIDE-EFFECTS AND SPECIAL PRECAUTIONS
When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, or when given intranasally, corticosteroids may be absorbed in sufficient amounts to cause systemic effects. Prolonged application to the eye of preparations containing corticosteroids has caused raised intra-ocular pressure and reduced visual function.
The following additional local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with high potency corticosteroids such as Betamethasone valerate cream. These reactions are listed in an approximately decreasing order of occurrence: dryness, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae, and miliaria.
PRESENTATION
Collapsible tube of 15 gm.
STORAGE
Store below 30°C, in a dry place protected from light.
Keep out of reach of children.
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
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