

BEZONE OINTMENT 0.1% W/W

BEZONE OINTMENT 0.1% w/w: A semi-transparent, unctuous, off-white ointment.

PHARMACOLOGY:

Corticosteroids produce anti-inflammatory, antipruritic and vasoconstrictor actions following topical application. The activity of the drugs is thought to result at least in part from binding with a steroid receptor. Corticosteroids decrease inflammation by stabilizing leukocytes lysosomal membranes; preventing the release of destructive acid hydrolases from leukocytes; inhibiting macrophage accumulation in inflamed areas; reducing leukocyte adhesion to capillary endothelium; reducing capillary wall permeability and edema formation; decreasing complement components; antagonizing histamine activity and release of kinin from substrates; reducing fibroblast proliferation, collagen deposition, subsequent scar tissue formation and possibly by other mechanism as yet unknown.

PHARMACOKINETICS:

Percutaneous penetration of corticosteroids varies among individual patients and can be increased by the use of occlusive dressings, by increasing the concentration of the corticosteroid and by using different vehicles. Following topical application of a corticosteroid to most areas of normal skin, only minimal amounts of the drug reach the dermis and subsequently the systemic circulation. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

COMPOSITION:

Each gram contains:

BEZONE OINTMENT 0.1% w/w : Each gram contains Betamethasone Valerate equivalent to 1.0mg Betamethasone.

INDICATIONS:

Eczema including atopic, infantile, and discoid eczemas. Prurigo nodularis. Psoriasis (excluding widespread plaque psoriasis). Neurodermatoses including lichen simplex, lichen planus. Seborrhoeic dermatitis. Contact sensitivity reactions. Discoid lupus erythematosus. An adjunct to systemic steroid therapy in generalised erythroderma. Insect bite reactions. Prickly heat.

ROUTE OF ADMINISTRATION:

External, locally applied.

DOSAGE/ADMINISTRATION:

Adults, Elderly and Children over 1 year

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice daily for up to 4 weeks until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient.

In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betamethasone valerate can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions; thereafter, improvement can usually be maintained by regular application without occlusion.

If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.

Therapy with Betamethasone valerate should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy.

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of Betamethasone valerate.

Recalcitrant dermatoses – patients who frequently relapse.

Once an acute episode has been treated effectively with a continuous course of topical corticosteroid, intermittent dosing (once daily, twice weekly, without occlusion) may be considered. This has been shown to be helpful in reducing the frequency of relapse. Application should be continued to all previously affected sites or to known sites of potential relapse. This regime should be combined with routine daily use of emollients. The condition and the benefits and risks of continued treatment must be re-evaluated on a regular basis.

Children

Betamethasone valerate is contraindicated in children less than one year of age. Children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults.

Care should be taken when using Betamethasone valerate to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly

Differences in responses between the elderly and younger patients have not been identified. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment

In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

ADVERSE EFFECTS:

Local side effects may occur includes burning, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, increased hair growth, thinning of the skin and growth of vellus hair and perioral dermatitis in young women. Maceration of the skin, secondary infection, skin atrophy, striae and miliria may occur more frequently with occlusive dressings. Systemic side effects may also occur such as hyperglycemia, glycosuria, features of hypercorticism and HPA axis suppression. These effects are likely to occur in infants and children, and if occlusive dressing is used. Treatment of psoriasis may provoke the pustular form of the disease

INTERACTIONS WITH OTHER MEDICAMENTS:

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

PRECAUTIONS/WARNINGS:

If skin irritation or contact dermatitis occurs, the medication should be discontinued and appropriate therapy should be initiated. Sufficient systemic absorption may occur to produce the features of hypercorticism if topical corticosteroids are applied over an extensive area of the skin. Indiscriminate use in pruritus may cause a rebound exacerbation of the condition and may occur when the treatment is stopped. Long term use of Bezone Ointment should be avoided in children as adrenal suppression can occur even without occlusion. Bezone Ointment should not be used on the face unless there is a specific indication. Do not use on eyes, in the ano-genital region and on broken or infected skin including cold sores, acne and athlete's foot. Corticosteroids should never be used in the presence of infection except in conjunction with effective chemotherapy.

PREGNANCY AND LACTATION:

Safe use of topical corticosteroids during pregnancy has not been established and should not be used in large amounts or for prolonged periods in pregnant women. Although there are no adequate and controlled studies to date in human, potent corticosteroids have been shown to be teratogenic in animals following topical application. Topical corticosteroids should be used during pregnancy only when the potential benefits justify the possible risks to the fetus. It is not known whether topical corticosteroids are distributed into milk. They should be used with caution in nursing women.

CONTRAINDICATIONS:

Topical corticosteroids are not recommended for infants under one year old. They should be used with caution and occlusive dressings should not be used in patients with primary skin infection. Topical corticosteroids should not be used for skin atrophy, pre-existing acne vulgaris, perioral dermatitis; primary cutaneous viral infection (eg. Herpes simplex, chicken pox); tuberculosis of the skin, vaccinia, varicella and rosacea. It is contraindicated in those patients with a history of hypersensitivity to Bezone Ointment or any of its component.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE:

Overdosage of corticosteroids may cause adrenal atrophy and show signs of Cushing's syndrome, with moon face, striae, acne and buffalo hump. Symptomatic treatment should be given. The drug should be slowly withdrawn where possible.

PHARMACEUTICAL INFORMATION / PACKAGE:

- Description** : BEZONE OINTMENT 0.1% w/w: a semi-transparent, unctuous, off-white ointment.
Packing Size : 15g aluminium tubes
Storage : Store in the original package and in a dry place. Do not store above 30°C. Protect from light. Keep out of reach of children.
Shelf Life : 3 years from date of manufacturing.

Manufacturer & Product Registration Holder:
MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,
Pulau Pinang, Malaysia.

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