For the use only of Registered Medical Practitioner or a Hospital or a Laboratory.

BETA-S®

बिटा-एस

Betamethasone Valerate 0.1% + Salicylic Acid 3%

ACTIONS:

Betamethasone Valerate: Betamethasone Valerate is a synthetic adrenocorticosteroid for dermatologic use. Betamethasone, an analog of Prednisolone, has a high degree of Glucocorticoids activity and a slight degree of mineralocorticoid activity. Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions.

Betamethasone is a Glucocorticoid receptor agonist. This leads to changes in genetic expression once this complex binds to the GRE (Glucocorticoid Response Element). The anti-inflammatory actions of corticosteroids are thought to involve lipocortins, phospholipase A2 inhibitory proteins which, through inhibition arachidonic acid, control the biosynthesis of prostaglandins and leukotrienes. The immune system is suppressed by corticosteroids due to a decrease in the function of the lymphatic system, a reduction in immunoglobulin and complement concentrations, the precipitation of lymphocytopenia, and interference with antigen-antibody binding. Betamethasone binds to plasma transcortin, and it becomes active when it is not bound to transcortin.

Salicylic Acid: Salicylic Acid is a keratolytic agent, meaning it works by softening keratin, a protein in the structure of the top layer of skin.

PHARMACOKINETICS:

Betamethasone Valerate: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. 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 metabolized 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.

Salicylic Acid: Salicylic acid may be percutaneously absorbed. However, there is no evidence of any systemic absorption from the use of Salicylic Acid Ointment.

INDICATIONS:

BETA-S Ointment is indicated for the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as Psoriasis, Chronic atopic dermatitis, Neurodermatitis , Chronic lichenified eczema, Lichen planus, Lichen simplex, Non-ballous ichthysiform erythroderma etc.

DOSAGE & ADMINISTRATION:

A thin film of BETA-S Ointment should be applied to cover completely the affected area. The ointment should be massaged gently and thoroughly into the skin. The usual frequency of application is 2-3 times daily.

CONTRAINDICATIONS:

BETA-S Ointment is contraindicated in viral diseases including vaccinia, varicella, herpes simplex, and fungal infections; also, tuberculosis of the skin. Hypersensitivity to any one of the components of BETA-S Ointment is a contraindication to its use.

ADVERSE EFFECTS:

The following local adverse skin reactions have been reported with the use of topical steroids; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. In addition, the salicylic acid component may cause local reddening of the skin, desquamation, pruritus and smarting. Continuous application of salicylic acid preparations to the skin may cause dermatitis. Hypersensitivity to salicylic acid may occur.

WARNINGS & PRECAUTIONS:

This drug should not be used in or near the eyes since BETA-S is not formulated for ophthalmic use. Avoid contact with mucous membranes. As well, keep BETA-S away from the genital area and other orifices.

Pediatrics: Any of the side effects that have been reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. Systemic absorption of topical corticosteroids or salicylic acid will be increased if extensive body surface areas are treated or if the occlusive technique is used. Suitable precautions should be taken under these conditions or when long-term use is anticipated, particularly in infants and children. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and to exogenous corticosteroid effects than mature patients because of a greater absorption due to a larger skin surface area to body weight ratio. Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with growth and development of children. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches, and bilateral papilledema.

Pregnancy and lactation: Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PRESENTATION:

20 gm ointment

Manufactured by:

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