## **Betamethasone Valerate**

**Introduction:** Betamethasone is a moderately potent glucocorticoid steroid with antiinflammatory and immunosuppressive properties.

**Mechanism of action:** Betamethasone Valerate is a glucocorticoid receptor agonist. The antiinflammatory 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 antigenantibody binding. Betamethasone Valerate binds to plasma transcortin, and it becomes active when it is not bound to transcortin.

**Pharmacology:** Betamethasone Valerate and its derivatives, betamethasone sodium phosphate and betamethasone acetate, are synthetic glucocorticoids. Used for its antiinflammatory or immunosuppressive properties, betamethasone is combined with a mineralocorticoid to manage adrenal insufficiency and is used in the form of betamethasone benzoate, betamethasone dipropionate, or betamethasone valerate for the treatment of inflammation due to corticosteroid-responsive dermatoses. Betamethasone Valerate and clotrimazole are used together to treat cutaneous tinea infections.

Indications: Betamethasone valerate is a medium potency topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp.

(An ISO 9001: 2008 Certified Company)

**Dosage:** For application to the scalp invert can and dispense a small amount of Luxíq onto a saucer or other cool surface. Do not dispense directly onto hands as foam will begin to melt immediately upon contact with warm skin. Pick up small amounts of foam with fingers and gently massage into affected area until foam disappears. Repeat until entire affected scalp area is treated. Apply twice daily, once in the morning and once at night.

As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary

**Side effects:** Stinging, burning, itching, irritation, dryness, or redness of the skin may occur when this medication is first applied to the skin. These effects should disappear in a few days as your body adjusts to the medication. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

**Precautions: General:** Systemic absorption of topical corticosteroids has caused reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, Betamethasone valerate should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation, as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, use of Betamethasone valerate

**Pregnancy Category C:** Betamethasone valerate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Many drugs are excreted in human milk; caution should be exercised when Betamethasone valerate is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

Hypothalamic-pituitary-adrenal (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 an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

**Contraindications:** Betamethasone valerate is contraindicated in patients who are hypersensitive to betamethasone valerate, to other corticosteroids, or to any ingredient in this preparation.

How supplied: Customized as per request.