

PRODUCT MONOGRAPH

VALISONE SCALP LOTION

(Betamethasone 17-Valerate)

Glucocorticoid

**Valeo Pharma Inc.
Kirkland, Quebec**

**DATE OF PREPARATION:
May 28, 2002**

STRUCTURAL FORMULA AND CHEMISTRY

Betamethasone Valerate (N.F.) is:

9 α -fluoro-11 β , 17, 21-trihydroxy-16 β -methylpregna-1,
4-diene-3, 20-dione 17-valerate



NAME OF DRUG

VALISONE SCALP LOTION

THERAPEUTIC OR PHARMACOLOGICAL CLASSIFICATION

Glucocorticoid

INDICATIONS

The management of dermatoses of the scalp. May also be used in corticoid responsive dermatoses.

CONTRAINDICATIONS

Tuberculosis of skin, herpes simplex, varicella, vaccinia, superficial fungus or yeast infections. Patients with a history of sensitivity reactions to any of its components. Application in or near the eyes should be avoided.

WARNINGS AND PRECAUTIONS

Corticosteroids are known to be absorbed percutaneously in patients under prolonged treatment, with extensive body surface treatment or particularly in those using the occlusive dressing technique on large areas of the body. In such cases, it is recommended that kidney function studies such as B.U.N. be carried out prior to treatment and regularly throughout the course of treatment.

Pregnancy and Lactation: Since safety of topical corticosteroids 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.

Children: 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 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 Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. 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. Use of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen.

When long-term topical treatment under occlusive dressings is necessary, small dosages, rotation of sites and intermittent therapy should be considered.

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

In the presence of infection, Valisone Scalp Lotion should be superseded by suitable antibacterial agents until the infection has cleared.

This lotion contains isopropyl alcohol, and may cause stinging or burning upon application to abraded or sun-burned skin. Do not use in or near eyes.

ADVERSE REACTIONS

With use of topical corticosteroids, local reactions have been reported, namely, burning sensation, itching, irritation, dryness, hypertrichosis, acneiform eruptions, and hypopigmentation. Striae, secondary infection, atrophy, miliaria, folliculitis, and pyodermas also occur but more frequently with use of occlusive dressings. Contact sensitivity to a particular dressing material or adhesive may occur occasionally.

Overdose: Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

PHARMACOLOGY

Betamethasone Valerate (N.F.)

Clinical trials and extensive experience now available have established the effective activity of betamethasone valerate in the suppression of inflammatory reactions, prompt and pro-longed control of pruritus, erythema, swelling, and infiltration, which are common manifestations of allergic conditions. Reduction of scratching decreases the likelihood of exacerbating the lesions or producing secondary infection. Clinical trials by numerous dermatologists who

have used betamethasone valerate in various localized and generalized corticosteroid-responsive diseases, indicated a high incidence of good to excellent results, either by inunction or under occlusive dressings.

DOSAGE AND ADMINISTRATION

Apply a small amount on the affected skin two or three times daily. Refractory lesions of psoriasis and other deep-seated dermatoses such as lichen simplex chronicus, hypertrophic lichen planus, atopic dermatitis, chronic eczematous and lichenified hand eruptions, and recalcitrant pustular eruptions on the palms and soles will respond better to topical corticosteroids when used with the hydration technique of occlusive dressing described below.

Occlusive Dressing Technique

1. Apply a thick layer of medication over the entire surface of the lesion under a light gauze dressing and cover it with a pliable, transparent, impermeable, plastic material well beyond the edges of the treated area.
2. Seal the edges to the normal skin by adhesive tape or other means.
3. Leave the dressing in place one to three days and repeat the procedure three or four times as needed.

With this method of treatment, marked improvement often is seen in a few days. However, this technique requires closer supervision

of the patient since occasionally miliary eruptions or folliculitis develop in the skin under an occlusive dressing, requiring removal of the plastic cover and/or discontinuance of this method of treatment.

AVAILABILITY

Each mL of lotion contains betamethasone 1mg (as valerate USP).

Nonmedicinal ingredients: carbomer 934P, isopropanol, sodium hydroxide and purified water.

Valisone Scalp Lotion is packaged in plastic squeeze bottles of 30 and 75mL.

Store between 2 to 30°C.