VALECORT S

Scalp Application

Composition

Betamethasone (as valerate)	0.1%
Salicylic acid	3 %

Action

Valecort -S Scalp Application contains the highly effective topical corticosteroid, Betamethasone 17-valerate. Valecort -S Scalp Application exerts rapid anti-inflammatory as well as potent antipruritic and vasoconstrictive effects. Valecort -S Scalp Application has shown to produce desquamation of the horny layer of skin while not effecting qualitative or quantitative changes in the structure of the viable epidermis. The mechanism of action has been attributed to dissolution of intercellular cement substance.

Indications

Valecort -S Scalp Application is a corticosteroid-responsive dermatoses such as psoriasis, seborrhea inflammatory conditions associated with severe dandruff, removal of excessive keratin in hyperkeratosis skin disorders, including verrucae, and the various ichthyosis (vulgaris, sex-linked and lamellar), keratosis Palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, psoriasis (including body, scalp, palms and soles).

Contraindications

- Valecort -S Scalp Application should not be used in known hypersensitivity to the preparation or to other corticosteroids and in any patient known to be sensitive to salicylic acid.
- Valecort -S Scalp Application should not be used in children under 2 years of age.

Warnings

Pregnancy

Category C

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids; therefore, topical corticosteroids should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Infants born to mothers who have been treated during pregnancy with large amounts of corticosteroids or for prolonged periods of time should be observed carefully for signs of hypoadrenalism.

Nursing Mothers

It is not known whether topical application of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, caution should be exercised when topical corticosteroids are applied to nursing women.

Use in Pediatrics and children

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced Hypothalamic- pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients, because of a larger skin surface area to body weight ratio. Therefore, application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Prolonged use over large areas, especially in children and those patients with significant renal or hepatic impairment could result in salicylism. Concomitant use of other drugs, which may contribute to elevated serum salicylate levels, should be avoided where the potential for toxicity is present. In children under 12 years of age and those patients with renal or hepatic impairment, the area to be treated should be limited and the patient monitored closely for signs of salicylate toxicity: nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnea, diarrhea, psychic disturbances.

In the event of salicylic acid toxicity, the use of this drug should be discontinued. Fluids should be administered to promote urinary excretion. Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate.

The following tests may be helpful in evaluating the HPA axis suppression:

- Urinary free control test
- ACTH stimulating test

Adverse Reactions

Adverse Reactions of a local nature have been reported with topical corticosteroids. These include a burning and/or stinging sensation, pustules, tingling, and folliculitis. Itching, tightness, dermatitis, tenderness, headache, hair loss, and eye irritation, have been reported infrequently.

The following local adverse reactions have been reported infrequently because of the use of topical corticosteroids on other areas of the body and are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. Excessive erythema and scaling conceivably could result from using Valecort -S Scalp Application on open skin lesions.

Precautions

If sensitization or irritation occurs, discontinue use.
In the presence of an infection, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response is not obtained promptly, the use of this preparation should be temporarily discontinued, until the infection has been controlled. Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients.

The presence of other medical problems may affect the use of the drug especially:
Cataracts or Glaucoma-Corticosteroids may make these medical problems worse, especially when stronger Corticosteroids are used in the eye area.

Diabetes mellitus (sugar diabetes) - too much use of Corticosteroids may cause a loss of control of diabetes by increasing blood and urine glucose. However, this is not likely to happen when topical Corticosteroids are used for short time.

Infection or sores at the place of treatment (unless your doctor also prescribed medicine for the infection) or Tuberculosis-Corticosteroids may make exiting infections worse or cause new infections.

Skin conditions that cause thinning of skin with easy bruising-Corticosteroids may make thinning of the skin worse.
If HPA axis suppression is noted, an attempt to reduce the frequency of application made. Recovery of the HPA axis function is generally prompt and complete upon discontinuation of the drug.

Dosage and Administration

A small quantity of the lotion should be applied to the affected area of the skin or scalp and massage lightly until disappears in the morning and evening until improvement occurs. It may then be possible to maintain this improvement by applying once daily or less frequently.

Over Dosage

Topical applied of this drug can be absorbed in sufficient amount to produce systemic effects. If toxicity occurs fluids should be administered to promote urinary excretion.

Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate

Presentation
Plastic bottle of 30 ml