VALECORT G

Cream & Ointment

Composition

Valecort -G Cream/Ointment

Each gram contains:

Betamethasone (as valerate)	0.1%
Gentamicin (as sulfate)	0.1%

Action

Valecort -G contains the highly effective topical corticosteroid, Betamethasone 17-valerate. Valecort -G exerts rapid anti-inflammatory as well as potent antipruritic and vasoconstrictive effects. It is effective in the treatment of difficult inflammatory and allergic dermatoses such as resistant psoriasis, lichen planus, lichen simplex chronicus and eczema of the hands.

Valecort -G also contains Gentamicin, a broad-spectrum aminoglycoside antibiotic that makes it particularly effective in dermatoses complicated by secondary bacterial skin infection. Compared to other antibiotics used to treat topical infections, Gentamicin is associated with a low incidence of sensitization.
Valecort -G is available as a water miscible cream or as an ointment.

Indications

- Valecort -G is indicated for the topical treatment of corticosteroid-responsive inflammatory, pruritic and allergic dermatoses where secondary bacterial infection is present or is likely to be present including eczema (e.g. atopic, infantile, discoid and stasis eczemas), prurigo, psoriasis, neurodermatoses (including lichen simplex chronicus), lichen planus, seborrheic dermatitis, intertrigo, contact sensitivity reactions, discoid lupus erythematosus and generalized erythroderma.
- Valecort -G used in the management of anal and vulval pruritus and otitis externa.

Contraindications

- Known hypersensitivity to the preparation
- Topical corticosteroids are contraindicated in fungal infections, tuberculosis of the skin, vaccinia, varicella and herpes simplex.
- This preparation should not be applied in the external auditory canal of patients with perforated eardrum. This preparation is not intended for ophthalmic use.

Warnings

Ototoxicity and nephrotoxicity have been reported with the topical use of Gentamicin. The likelihood of their occurrence may be increased if the patient is being concurrently treated with an aminoglycoside antibiotic.

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, should be observed carefully for signs of hypoadrenalism.

Nursing Mothers

It is unknown 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.

Paediatric Use

Paediatric 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.

Adverse Reactions

The following local adverse reactions have been reported infrequently and are listed in an approximate decreasing order of occurrence: burning, itching, and irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, and allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.
It should be noted that these adverse reactions could occur more frequently with occlusive dressings, tight-fitting diapers or plastic pants.

Signs of a sensitivity reaction to Gentamicin may also appear, usually in the form of a low-grade reddening with swelling, dry scaling or itching, or simply as a failure to heal. During long-term use of Gentamicin-containing preparations, periodic examination for such signs is recommended. If they occur, patients should be advised to discontinue treatment.
Allergic cross-reactions, which could prevent the future use of any or all of the following antibiotics for the treatment of infections: kanamycin, paromomycin and streptomycin

Precautions

If sensitization or irritation occurs, discontinue use.

If the sensitivity attributed to the antibiotic component, the patient should avoid Gentamicin-containing preparations in the future.

When using Gentamicin-containing preparations to control secondary infection in chronic dermatoses, it should be borne in mind that the skin is more liable to become sensitive to other substances, including Gentamicin.

If local infection should continue or become severe, or in the presence of systemic infection, appropriate antimicrobial therapy should be instituted. If a favourable response is not obtained, the use of this preparation should be temporarily discontinued, until the infection has been controlled.

If extensive areas are treated or if the occlusive technique is used, the possibility exists of increased systemic absorption and suitable precautions will be required in patients with electrolyte imbalance, gastrointestinal disturbances, diabetes, myopathy, cataract, renal or hepatic impairment, osteoporosis, and hemorrhage.

As with other antibiotic-containing topical preparations, prolonged use may result in an overgrowth of non-susceptible fungi. Appropriate measures should be taken if this occurs.
Because of the concern of possible nephrotoxicity and ototoxicity associated with Gentamicin, this preparation should not be used over a wide area or for extended periods.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients.

Conditions that augment systemic absorption include the application of potent steroids, use over large surface areas, prolonged use, and the use of occlusive dressings, tight-fitting diapers and plastic pants. Such patients should be periodically evaluated for evidence of HPA axis suppression. This is performed using urinary free cortisol and adrenocorticotropic hormone (ACTH) stimulation tests. If HPA axis suppression is noted, an attempt should be made either to reduce the frequency of application, or to substitute a less potent steroid. Recovery of the HPA axis function is generally prompt and complete upon discontinuation of the drug.

Application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Dosage and Administration

A thin layer should be applied gently to the affected area once or twice daily, until improvement occurs. It may then be possible to maintain this improvement by applying once daily or less frequently.
Valecort -G cream is recommended for use on moist or weeping skin surfaces.
Valecort -G ointment is especially appropriate for use on dry, lichenous or scaly lesions, to facilitate penetration.

Presentation

Valecort -G Cream/Ointment
Tube of 15 grams