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SEBOWASH Shampoo (Fluocinolone acetonide)

Composition

Fluocinolone Acetonide IP .....0.01% w/v

Dosage Form

Shampoo

Pharmacology

▶ Pharmacodynamics

Fluocinolone acetonide (6 alpha, 9-Difluro-11 beta, 16 alpha, 17,21 -tetrahydroxypregna-1,4-diene-3, 20-dione cyclic 16,17-acetal with acetone) is a synthetic fluorinated corticosteroid for topical dermatologic use. Like other topical corticosteroids, fluocinolone acetonide has anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2. Fluocinolone acetonide has low to medium potency, compared to other topical corticosteroids.

▶ Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin while inflammation and/or other disease processes in the skin increase percutaneous absorption.

Indications

SEBOWASH Shampoo is indicated for the treatment of seborrhoeic dermatitis of the scalp. This product has not been proven effective in other corticosteroid-responsive dermatoses.

Dosage And Administration

The SEBOWASH Shampoo bottle should be shaken well prior to use. The required amount of SEBOWASH Shampoo should be applied to the scalp area once daily, massaged until it lathers, and then allowed to remain on the scalp for approximately 5 minutes. The hair and scalp should then be rinsed thoroughly with water.

Contraindications

SEBOWASH Shampoo is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

Warnings And Precautions

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticoid insufficiency after withdrawal of treatment.
Manifestations of Cushing's syndrome, hyperglycaemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.
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. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary-free cortisol tests. Patients receiving superpotent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA 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 corticosteroid. Infrequently, signs and symptoms of glucocorticoid insufficiency may occur, requiring supplemental systemic corticosteroids.
If irritation develops, SEBOWASH Shampoo should be discontinued and appropriate therapy instituted.
Allergic contact dermatitis with corticosteroids is usually diagnosed by 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.
If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favourable response does not occur promptly, use of SEBOWASH Shampoo should be discontinued until the infection has been adequately controlled.

▶ Pregnancy

Pregnancy Category C
Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.
There are no adequate and well-controlled studies in pregnant women or teratogenic effects from fluocinolone acetonide shampoo. Therefore, SEBOWASH Shampoo should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

▶ Lactation

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are secreted in human milk, caution should be exercised when SEBOWASH Shampoo is administered to a nursing woman.

▶ Paediatric Use

Safety and effectiveness in children and infants have not been established. Because of a higher ratio of skin surface area to body mass, paediatric patients are at a greater risk of HPA axis suppression than adults

when they are treated with topical corticosteroids. They are, therefore, also at a greater risk of glucocorticoid insufficiency after withdrawal of treatment and of Cushing's syndrome while on treatment. Adverse effects, including striae, have been reported with inappropriate use of topical corticosteroids in infants and children.
HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

Undesirable Effects

The following local adverse reactions have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: dryness, folliculitis, acneiform eruptions, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, miliaria, burning, itching, irritation, and hypopigmentation.
If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024.
By reporting side effects you can help provide more information on the safety of this product.

Overdosage

Topically applied fluocinolone acetonide shampoo can be absorbed in sufficient amounts to produce systemic effects (See WARNINGS AND PRECAUTIONS).

Shelf-Life

30 months

Storage And Handling Instructions

Store in a cool dry place.

Packaging Information

SEBOWASH Shampoo.....bottle of 100 ml

How To Use Sebowash

Shake the SEBOWASH Shampoo bottle well.
Wet the hair and scalp thoroughly, apply sufficient amount of SEBOWASH Shampoo, and massage into the scalp. (Please note that this product does not contain drying detergents and, therefore, produces minimal lathering.)
Allow the shampoo to remain on the scalp for 5 minutes. (Note: This is necessary for effective treatment.)
Rinse thoroughly with water. Conditioner is not needed.

Repeat the above instructions daily for 2 weeks.

Information For Patients

SEBOWASH Shampoo is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes. In case of contact, wash eyes liberally with water.
This medication should not be used for any disorder other than that for which it was prescribed.
The treated scalp area should not be bandaged or otherwise covered or wrapped so as to be occlusive, unless directed by the physician.
Patients should report to their physician any signs of local adverse reactions.

Last Updated: Aug 2012
Last Reviewed: Sep 2017

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