1. Patients using topical corticosteroids should receive the following information and instructions:

   Information for Patients:

   Patients should promptly report to their physician any worsening of their skin condition.

   In a vehicle-controlled study for the treatment of psoriasis of the scalp in adults, after 21 days of treatment, 60% of patients on active treatment and 21% of patients on the drug vehicle had excellent to cleared clinical response.

   Patients experiencing an exacerbation of atopic dermatitis after 5 days of fluocinolone acetonide topical oil use. Importantly, the bulk peanut oil NF, used in fluocinolone acetonide topical oil, is heated at 475°F for at least 15 minutes, which should provide for adequate decomposition of allergenic proteins.

   INDICATION AND USAGE

   Fluocinolone acetonide topical oil is a low to medium potency corticosteroid indicated:

   In adult patients for the treatment of psoriasis of the scalp (Scalp Oil).

   CONTRAINDICATIONS

   Fluocinolone acetonide topical oil is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

   This product contains refined peanut oil NF (see PRECAUTIONS section).

   PRECAUTIONS

   General: Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushings syndrome, hyperglycemia, and glucocorticosteroids 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. 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 glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

   For information regarding the use of corticosteroids in patients with diabetes mellitus, see WARNINGS-Endocrine and Metabolic Effects section.

   Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than noting a clinical exacerbation, which may occur with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic testing. One peanut sensitive child experienced a flare of his atopic dermatitis after 5 days of twice daily treatment with fluocinolone acetonide topical oil (see CLINICAL STUDIES section).

   If wheal and flare type reactions (which may be limited to pruritus) or other manifestations of hypersensitivity develop, fluocinolone acetonide topical oil should be discontinued immediately and appropriate therapy instituted.

   For information regarding the use of corticosteroids in patients with diabetes mellitus, see WARNINGS-Endocrine and Metabolic Effects section.

   If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of fluocinolone acetonide topical oil should be discontinued until the infection has been adequately controlled.

   Fluocinolone acetonide topical oil is formulated with 48% refined peanut oil NF.

   Physicians should use caution in prescribing fluocinolone acetonide topical oil for peanut sensitive individuals.

   Information for Patients: Patients using topical corticosteroids should receive the following information and instructions:

   1. This medication 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 literally with water.

   2. This medication should not be used for any disorder other than that for which it was prescribed.

   3. Patients should promptly report to their physician any worsening of their skin condition.

   4. Parents of pediatric patients should be advised not to use fluocinolone acetonide topical oil in the treatment of diaper dermatitis. Fluocinolone acetonide topical oil should not be applied to the diaper area as diapers or plastic pants may constitute occlusive dressing.

   Rx only

   NDC 51672-1357-8

   For Topical Use Only

   Not for Oral, Ophthalmic, or Intravaginal Use

   DESCRIPTION

   Fluocinolone Acetonide Topical Oil, 0.01% contains fluocinolone acetonide (tris[(2-chloro-1-methyl-1H-imidazol-1-yl)methyl]acetone}, a synthetic corticosteroid for topical dermatologic use. This formulation is also marketed as Fluocinolone Acetonide Topical Oil, 0.01% for use as body oil for atopic dermatitis in adults and for moderate to severe atopic dermatitis in pediatric patients 2 years and older and as fluocinolone acetonide oil, 0.01% for chronic eczematous external otitis.

   Chemically, fluocinolone acetonide is C26H24O4. It has the following structural formula: \[ \alpha-\text{H}

   Fluocinolone acetonide in Fluocinolone Acetonide Topical Oil, 0.01% has a molecular weight of 452.50. It is a yellow crystalline powder that is odorless, stable in light, and melts at 270°C with decomposition; soluble in alcohol, acetone and methanol, slightly soluble in chloroform, insoluble in water.

   Each gram of fluocinolone acetonide topical oil contains approximately 0.11 mg of fluocinolone acetonide in a blend of oils, which contains isopropyl alcohol, isopropyl myristate, light mineral oil, dieth-2, and refined peanut oil.

   Each packaged product contains 2 shower caps. The shower cap is made of low density polyethylene material with rubber elastic.

   CLINICAL PHARMACOLOGY

   Like other topical corticosteroids, fluocinolone acetonide has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins counteract the detrimental effects of arachidonic acid and related compounds such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

   Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusion of topical corticosteroids can enhance penetration. Topical corticosteroids can be absorbed from normal intact skin. Also, inflammation and/or other disease processes in the skin can increase percutaneous absorption.

   Fluocinolone acetonide topical oil is in the low to medium range of potency as compared with other topical corticosteroids.

   CLINICAL STUDIES

   In a vehicle-controlled study for the treatment of psoriasis of the scalp in adults, after 21 days of treatment, 60% of patients on active treatment and 21% of patients on the drug vehicle had excellent to cleared clinical response.

   Open-label safety studies on 33 children (20 subjects ages 2 to 6 years, 13 subjects ages 7 to 12 years) with moderate to severe atopic dermatitis, and having body surface area involvement greater than 75% in 18 patients, and 50% to 75% in 15 patients, were treated with fluocinolone acetonide topical oil twice daily for 4 weeks. Morning pre-stimulation cortisol level and post-Cortrosyn stimulation cortisol level were obtained in each subject at the beginning of the trial and at the end of 4 weeks of treatment. At the end of treatment, 4 out of 18 subjects aged 2 to 5 years showed low pre-stimulation cortisol levels (0.2 to 6.6 µg/dl, normal: cortisol > 7 µg/dl) but all had normal responses to 0.25 mg of Cortrosyn stimulation (cortisol > 18 µg/dl).

   A clinical study was conducted to assess the safety of fluocinolone acetonide topical oil, which contains refined peanut oil, on subjects with known peanut allergies. The study enrolled 13 patients with atopic dermatitis, 6 to 17 years of age. Of the 13 patients, 9 were RadiaKologiebogenTest (RAT) positive to peanuts and 4 had no peanut sensitivity (control). The study evaluated the responses to both prick test and patch test utilizing refined peanut oil NF, fluocinolone acetonide topical oil and histamine/saline controls, on the 13 individuals. These subjects were also treated with fluocinolone acetonide topical oil twice daily for 7 days. Prick test and patch test results for all 13 patients were negative to fluocinolone acetonide topical oil and the refined peanut oil. One of the 9 peanut-sensitive patients experienced an exacerbation of atopic dermatitis after 5 days of fluocinolone acetonide topical oil use. Importantly, the bulk peanut oil NF, used in fluocinolone acetonide topical oil is heated at 475°F for at least 15 minutes, which should provide for adequate decomposition of allergenic proteins.

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Fluocinolone acetonide topical oil is formulated with 48% refined peanut oil NF. There are no adequate and well-controlled studies in pregnant women on teratogenic effects of fluocinolone acetonide topical oil. Some corticosteroids have been found to be genotoxic in various genotoxicity tests (i.e. the in vitro human peripheral blood lymphocyte chromosome aberration assay with metabolic activation, the in vivo mouse bone marrow micronucleus assay, the Chinese hamster micronucleus test and the in vitro mouse lymphoma gene mutation assay).

Drug Interactions: The simultaneous use of topically applied fluocinolone with other corticosteroids results in increased local absorption and may result in greater systemic effects. The use of fluocinolone acetonide topical oil for longer than 4 weeks or in children younger than 2 years of age should be avoided.

A post-marketing (open-label) safety study was conducted in 58 children to evaluate the local safety of fluocinolone acetonide topical oil when applied twice daily for 4 weeks to the face in children (2 to 12 years) with moderate to severe atopic dermatitis (see Table of Incidence of Adverse Reactions).