Capex® Shampoo
(fluocinolone acetonide)
Topical Shampoo, 0.01%—Rx only
For Topical Use Only
Not for Ophthalmic Use

DESCRIPTION: Capex® Shampoo 0.01% is supplied as a shampoo formulation with a 12 mg fluocinolone acetonide capsule which is emptied into the shampoo base by the pharmacist at the time of dispensing. After mixing, Capex® Shampoo contains fluocinolone acetonide (6x,9-Difluoro-11β,16α, 17.21-tetrahydroxypregna-1,4-diene-3, 20-dione cyclic 16,17-acetal with acetonide), a synthetic fluorinated corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primarily synthetic steroids used topically as an anti-inflammatory and antipruritic agents.

Chemically, Capex® Shampoo mixture is C_{24}H_{30}F_2O_6. It has the following structural formula:

![Structural formula of Capex Shampoo](image)

Fluocinolone acetonide in Capex® Shampoo has the molecular weight of 452.50. It is a white crystalline powder that is odorless, stable in light and melts at 270°F with decompositon; soluble in alcohol, acetone and methanol; slightly soluble in chloroform; insoluble in water.

Each fluocinolone capsule contains 12 mg of fluocinolone, 548 mg of dibasic calcium phosphate dihydrate USP, and 240 mg of talc USP. The shampoo base contains aluminum acetate dibasic, benzalkonium chloride solution, boric acid, citric acid anhydrous, cocamido-ether-sulfate complex, cocamine oxide, lauramide DEA, magnesium aluminum silicate, methylparaben, oat flour, propylene glycol, propylparaben, purified water, and fragrances, with D&C Yellow #10 and FD&C Blue #1 as coloring.

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 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 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. Occlusive dressings with 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. Capex® Shampoo is in the low to medium range of potency as compared with other topical corticosteroids.

CLINICAL STUDIES: In vehicle-controlled studies for the treatment of seborrheic dermatitis of the scalp, after 14 days of treatment, 84% of patients on active treatment and 29% of patients on the drug vehicle had cleared or markedly improved.

INDICATION AND USAGE: Capex® Shampoo is a low to medium potency corticosteroid indicated for the treatment of seborrheic dermatitis of the scalp. This product has not been proven to be effective in other corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Capex® Shampoo is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS: General: 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, hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying topical steroids 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. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. (See PRECAUTIONS-Pediatric Use.)

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.
2. Wash eyes liberally with water.
3. This medication should not be used for any disorder other than that for which it was prescribed.
4. The treated scalp area should not be bandaged or otherwise covered or wrapped so as to be occlusive, unless directed by the physician.
5. Patients should report to their physician any signs of local adverse reactions.

6. Discard contents after two (2) months.

Laboratory Tests: The following tests may be helpful in evaluating patients for HPA axis suppression:

ACTH stimulation test
A.M. plasma cortisol test
Urinary free cortisol test

ADVERSE REACTIONS:

• Work Capex Shampoo into a lather.
• Leave Capex Shampoo on your scalp for at least 5 minutes.
• Rinse your hair and scalp well with water.
• Do not bandage or cover your head after using Capex Shampoo unless your doctor tells you to.
• Tell your doctor if you develop irritation where you apply Capex Shampoo, or if your seborrheic dermatitis gets worse.

If irritation develops, Capex® 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 contact dermatitis is diagnosed or develops, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of Capex® Shampoo should be discontinued until the infection has been adequately controlled.

PATIENT INFORMATION

Before using Capex Shampoo, tell your doctor about all of your medical conditions, including:

• If you are pregnant or plan to become pregnant. It is not known if Capex shampoo can harm your unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.
• If you are breastfeeding or plan to breastfeed. It is not known if Capex Shampoo passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use Capex Shampoo.

Do not use other products containing a corticosteroid medicine with Capex Shampoo without talking to your doctor first.

How should Capex Shampoo be used:

1. This medication is to be used as directed by the physician. Do not get Capex Shampoo in your eyes.
2. Wash your hands before and after using Capex Shampoo unless your doctor tells you to.
3. The treated scalp area should not be bandaged or covered your head after using until the infection has been adequately controlled.

What are the possible side effects of Capex Shampoo?

Capex Shampoo is a prescription medicine used on the scalp to treat a skin condition called

The side effects of corticosteroids medicines used on the skin (topical) include:

• dry, itchy, and reddened skin
• burning or stinging at application site
• inflamed hair follicle
• acne
• thinning of skin

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Call your doctor for medical advice about side effects. You may report side effects to FDA at

1-800-FDA-1088

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What are the possible side effects of Capex Shampoo?
Arachidonic acid is released from membrane phospholipids by release of their common precursor arachidonic acid. Arachidonic acid is involved in the synthesis of eicosanoids, including prostaglandins, platelet-activating factor, leukotrienes, and TXA2.

It is postulated that these proteins, collectively referred to as lipocortins, play a role in the inhibition of phospholipase A2, thus blocking the formation of arachidonic acid and its metabolites, as well as the synthesis of eicosanoids.