Clobetasol Propionate

CLOFOAM

COMPOSITION

CLOFOAM
Clobetasol Propionate USP .....0.05% w/w
Also contains:
Absolute Alcohol..... 76.05% v/w

DOSAGE FORM

Thermolabile Foam

PHARMACOLOGY

Pharmacodynamics
Like other topical corticosteroids, clobetasol propionate foam has anti-inflammatory, antipruritic, and vasoconstrictive properties. The precise mechanism of the anti-inflammatory activity of topical steroids in the treatment of steroid-responsive dermatoses, in general, is uncertain. 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.

Pharmacokinetics

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

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Due to the fact that circulating levels are well below the level of detection, the use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary. They are metabolized, primarily in the liver, and are then excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS

CLOFOAM is a super-potent topical corticosteroid preparation indicated for short-term

topical treatment of the inflammatory and pruritic manifestations of:

- Moderate to severe corticosteroid-responsive dermatoses of the scalp.
- Mild to moderate plaque-type psoriasis of non-scalp regions, excluding the face and intertriginous areas.

Treatment beyond two consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

DOSAGE AND ADMINISTRATION

CLOFOAM should be applied to the affected scalp area twice daily, once in the morning and once at night. Invert the can and dispense a small amount of foam into the cap of the can. Dispensing directly onto hands is not recommended, as the foam will begin to melt immediately upon contact with warm skin. Move the hair away from the affected area of the scalp so that the foam can be applied to each affected area. Gently massage foam into affected scalp area until the foam disappears. Repeat until entire affected scalp area is treated.

Note: Apply the smallest amount possible that sufficiently covers the affected area(s). No more than 1½ capfuls of foam should be used at each application. Do not apply to the face, or intertriginous areas. Unless directed by a physician, **CLOFOAM** should not be used with occlusive dressings.

CONTRAINDICATIONS

CLOFOAM is contraindicated in patients who are hypersensitive to clobetasol propionate, to other corticosteroids, or to any ingredient in this preparation.

CLOFOAM is a super-high-potency topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks and amounts greater than 50 g/week should not be used. Use in pediatric patients under 12 years of age is not recommended.

WARNINGS AND PRECAUTIONS

Clobetasol propionate is a super-potent topical corticosteroid that has been shown to suppress the adrenal at 7.0 g of foam formulation per day. Lesser amounts of the same were not studied. Systemic absorption of topical corticosteroids has caused reversible adrenal suppression with the potential for glucocorticosteroid 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.

Conditions that augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of adrenal suppression. If adrenal suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see the 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.
The following tests may be helpful in evaluating patients for adrenal suppression: ACTH stimulation test, A.M. plasma cortisol test and urinary-free cortisol test.

If irritation develops, **CLOFOAM** should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing 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. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, use of **CLOFOAM** should be discontinued until the infection has been adequately controlled.

Pregnancy (Category C)

Teratogenic Effects
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 to laboratory animals. Clobetasol propionate has not been tested for teratogenicity by the topical route; however, it is absorbed percutaneously, and when administered subcutaneously, it was a significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent.

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. **CLOFOAM** should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Drugs of this class should not be used extensively on pregnant patients in large amounts, or for prolonged periods.
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 breast milk. Because many drugs are excreted in human milk, caution should be exercised when **CLOFOAM** is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of **CLOFOAM** in paediatric patients have not been established; therefore, use in children under 12 years of age is not recommended.
Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of adrenal suppression and Cushing's syndrome when they are treated with topical corticosteroids. Pediatric patients are therefore at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.
Adrenal suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric Use

Clinical studies of **CLOFOAM** did not include a sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experiences have not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

UNDESIRABLE EFFECTS

In a controlled pharmacokinetic study, 5 of 13 subjects experienced reversible suppression of the adrenals at any time during the 14 days of clobetasol propionate foam therapy to at least 20% of the body surface area. Of the 13 subjects studied, 1 of 9 with psoriasis was suppressed after 14 days and all 4 of the subjects with atopic dermatitis had abnormal cortisol levels indicative of adrenal suppression at some time after starting therapy with clobetasol propionate foam.
Systemic absorption of topical corticosteroids had produced reversible adrenal suppression, manifestations of Cushing’s syndrome, hyperglycaemia, and glucosuria in some patients.
In a controlled trial of 188 patients with psoriasis of the scalp, the only reported adverse reactions were one case each of dry skin, eczema, and skin hypertrophy. In larger controlled trials with other clobetasol propionate formulations, the most frequently reported adverse reactions have included burning, stinging, irritation, pruritus, erythema,

folliculitis, cracking and fissuring of the skin, numbness of the fingers, skin atrophy, and telangiectasia (all less than 2%).
The following additional local adverse reactions have been reported with topical corticosteroids, but they may occur more frequently with the use of occlusive dressings and higher potency corticosteroids such as clobetasol propionate. These reactions are listed in an approximate decreasing order of occurrence:
dryness, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae, and miliaria.

OVERDOSAGE

Topically applied **CLOFOAM** can be absorbed in sufficient amounts to produce systemic effects.

SHELF-LIFE

2 years

STORAGE AND HANDLING INSTRUCTIONS

Refrigerate before use.

Caution
FLAMMABLE. AVOID FIRE, FLAME, OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.

Keep out of reach of children.
Contents under pressure. Do not puncture or incinerate container. Do not expose to heat.

PACKAGING INFORMATION

CLOFOAM is supplied in a 30 gm aluminium can.

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 and should not be used longer than the prescribed period. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated scalp area should not be bandaged or otherwise covered or wrapped so as to be occlusive, unless directed by the physician.

4. Patients should report to their physician any signs of local adverse reactions.

DIRECTIONS FOR USE

1) Remove the transparent cap. Tamper evident seal.
2) Gently break the seal by pushing back the nozzle downwards.
3) Turn the can upside down. Press nozzle and remove a small amount of **CLOFOAM** into the cap (not more than 1½ capful).
   Caution: Do not dispense the foam in the upright position, as this will lead to loss of propellant. Also, do not dispense the foam directly onto your hands because it will begin to melt right away on contact with your warm skin.
4) Before using **CLOFOAM,** rinse your fingers in cold/tap water. Using your fingertips, gently massage **CLOFOAM** into the affected area on your scalp until the foam disappears. Let the foam work overnight or throughout the day. Repeat this procedure every morning and night, or as directed by your physician.
   Caution: Do not wash your hair immediately after applying **CLOFOAM.**
5) After applying **CLOFOAM,** wash your hands. Wash the cap before placing it back on the can.

Note: If the can feels warm or the foam seems runny, run the can under cold water.

Last updated: June 2010