Clobetasol Propionate Ointment USP, 0.05% US

No. only

FOR TOPICAL DERMATOLOGIC USE ONLY— NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE

DESCRIPTION
Clobetasol propionate ointment USP, 0.05% contains the active compound clobetasol propionate, a synthetic corticosteroid, for topical dermatologic use. Clobetasol, being a member of the 11-deoxycorticosteroids, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Chemically, clobetasol propionate is (11b,16a)-21-chloro-9β,11β,16α-tetrahydropregna-1,4-diene-3,20-dione, and has the following structural formula:

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Clobetasol propionate has the molecular formula C27H28ClO4 and a molecular weight of 467. It is a white or almost white crystalline powder miscible in water.

Clobetasol propionate ointment USP, 0.05% contains clobetasol propionate 0.5 mg/g in a base of propylene glycol, sorbitan sesquioleate, and white petrolatum.

CLINICAL PHARMACOLOGY

Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, a corticosteroid is thought to be, at least in part, the result of suppression of the release of prostaglandins from inflammatory cells with subsequent suppression of other mediators of inflammation such as histamine and leukotrienes by inhibiting the release of their common precursor, arachidonic acid.

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 with a water-permeable plastic wrap can increase absorption by about 2- to 4-fold. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other diseased processes in the skin may increase percutaneous absorption.

Studies performed with clobetasol propionate ointment indicate that it is in the super high range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE

Clobetasol propionate ointment USP, 0.05% is a super-high potency corticosteroid formulation indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Treatment frequently reduces symptoms of the disease that is sufficient to allow a gradual reduction in dosage, thereby avoiding potentially unnecessary exposure of the body to corticosteroid hormones. The drug should be used for the shortest possible duration consistent with good control and prevention of relapse. In localized disease involving large body areas, continuing therapy should be given only until all signs and symptoms of the disease have disappeared or until a more potent corticosteroid becomes necessary.

The use of clobetasol propionate ointment USP, 0.05% is not recommended for the treatment of scalp psoriasis or eczema because more potent corticosteroids are indicated for these conditions.

General

Clobetasol propionate ointment should not be used in the treatment of rosacea or psoriasis, or on the eyes, or in the scalp.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Once this has occurred, it will usually recover if the drug is withdrawn and the HPA axis suppressed function is noted by the presence of signs and symptoms of hypoadrenalism in patients hyperresponsive to ACTH. In patients hyperresponsive to ACTH, 2 weeks of drug suppression may be sufficient to establish HPA axis suppression and, thereby, produce withdrawal symptoms in some patients. Hydrocortisone is not as likely to suppress the HPA axis in this regard.

Patients applying topical steroids to large surface areas or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. Signs and symptoms of HPA axis suppression may include hypotension, weakness, memory loss, lethargy, mood changes, somnolence, hypoglycemia, and decreased carbohydrate tolerance. Patients receiving super-potent corticosteroids should be treated for more than 2 weeks at a time, and only small areas should be treated at any one time (e.g., one joint or the hand). Signs and symptoms of HPA axis suppression should be alleviated with the drug withdrawal or with 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.
Clobetasol propionate ointment is a super-high potency topical corticosteroid. It is used to treat skin conditions such as eczema, psoriasis, and certain allergies. This medication should not be used for any disorder other than that for which it was prescribed.

**DOSAGE AND ADMINISTRATION**

Topically applied clobetasol propionate ointment can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

**OVERDOSAGE**

In studies where geriatric patients (65 years of age or older, see PRECAUTIONS) have been treated with clobetasol propionate ointment for up to 101 days in US and non-US clinical trials, no adverse events have been reported that were attributed to clobetasol propionate ointment. In controlled clinical investigations, the most frequent adverse events reported for clobetasol propionate ointment were burning sensation, irritation, and itching in 0.5% of treated patients. Less frequent adverse reactions were stinging, cracking, erythema, folliculitis, numbness of fingers, skin atrophy, and telangiectasia. Cushing syndrome has been reported in infants and children. In controlled clinical investigations, the most frequent adverse events reported for clobetasol propionate ointment were burning sensation, irritation, and itching in 0.5% of treated patients. Less frequent adverse reactions were stinging, cracking, erythema, folliculitis, numbness of fingers, skin atrophy, and telangiectasia.

Cushing syndrome cannot be excluded in infants and children as a result of long-term use of topical clobetasol propionate formulations. The following additional local adverse reactions have been reported with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in an approximately decreasing order of frequency:

- Edema
- Hirsutism
- Hypertrichosis
- Purpura
- Striae
- Miliaria

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dose levels. There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. Clobetasol propionate ointment should not be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. However, there has been no evidence of fetal harm from the use of topical corticosteroids in pregnancy. The following test may be helpful in evaluating patients for HPA axis suppression:

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate. In a 2-year inhalation study in rats, clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay and the in vitro UDS (unscheduled DNA synthesis). Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay and the in vitro UDS (unscheduled DNA synthesis). Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay and the in vitro UDS (unscheduled DNA synthesis). Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay and the in vitro UDS (unscheduled DNA synthesis). Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay and the in vitro UDS (unscheduled DNA synthesis). Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay and the in vitro UDS (unscheduled DNA synthesis).