PRESCRIBING INFORMATION

PrDERMOVATE® SCALP APPLICATION
(Clobetasol Propionate USP in an aqueous-alcohol base)

Topical Corticosteroid

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Prescribing Information

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Topical Corticosteroid

Clinical Pharmacology

The corticosteroids are a class of compounds comprising steroid hormones secreted by the adrenal cortex and their synthetic analogs. In pharmacologic doses, corticosteroids are used primarily for their anti-inflammatory and/or immunosuppressive effects. Topical corticosteroids such as clobetasol propionate are effective in the treatment of corticosteroid-responsive dermatoses primarily because of their anti-inflammatory, anti-pruritic, and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their actions in each disease are uncertain.

Clobetasol propionate has been shown to have topical and systemic pharmacologic and metabolic effects characteristic of the corticosteroid class of drugs.

Indications and Clinical Use

DERMOVATE® (clobetasol propionate) Scalp Application is indicated in the topical therapy of recalcitrant corticosteroid-responsive dermatoses of the scalp,

including recalcitrant cases of psoriasis and seborrheic dermatitis.

Contraindications

DERMOVATE® (clobetasol propionate) Scalp Application is not indicated in the treatment of infected lesions of the skin if no anti-infective agent is used simultaneously, fungal and viral infections of the scalp (including herpes simplex, vaccinia and varicella) and tuberculous lesions of the skin. Clobetasol propionate scalp application is also contraindicated in patients who are hypersensitive to any of the components of the preparation. Clobestasol propionate is also contraindicated in dermatoses in children under one year of age, including dermatitis.

Warnings

DERMOVATE® (clobetasol propionate) Scalp Application should be used with caution in lesions close to the eye. Care is needed to ensure that the preparation does not enter the eye as glaucoma may result. Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

When DERMOVATE® Scalp Application is used over extensive areas for prolonged periods, it is possible that sufficient absorption may take place to give rise to adrenal suppression. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of larger skin surface area to body weight ratio. It is advisable, therefore, to use Clobetasol Propionate Scalp

Application for brief periods only, and to discontinue its use as soon as the lesion has resolved. No more than 50 millilitres of DERMOVATE® Scalp Application should be used per week.

Patients should be advised to inform subsequent physicians of their prior use of corticosteroids.

Precautions

General

Because the safety and effectiveness of DERMOVATE® (clobetasol propionate) Scalp Application has not been established in children, its use in this age group is not recommended.

DERMOVATE® Scalp Application should not be used near an open flame.

Prolonged use of topical corticosteroids may produce atrophy of the skin and of subcutaneous tissues. If this is noted, the use of the product should be discontinued.

Although hypersensitivity reactions are rare with topically applied corticosteroids, the drug should be discontinued and appropriate therapy initiated if there are signs of hypersensitivity.

Long-term continuous therapy with DERMOVATE® Scalp Application should be avoided, particularly in infants and children, as adrenal suppression can occur even without occlusion. Significant systemic absorption may occur when corticosteroids are applied over large areas of the body, especially under occlusive dressings. Because the degree of absorption of clobetasol propionate

when applied under occlusive dressing has not been measured, its use in this fashion is not recommended.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis, careful patient supervision is important.

Appropriate anti-microbial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. In cases of bacterial infections of the skin, appropriate antibacterial agents should be used as primary therapy. If it is considered necessary, the topical corticosteroid may be used as an adjunct to control inflammation, erythema and itching. If a symptomatic response is not noted within a few days to a week, the local application of corticosteroid should be discontinued until the infection is brought under control.

Use in Pregnancy and Lactation

Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development. The relevance of this finding to human beings has not been established. The safe use of clobestasol propionate during lactation has not been established. However, the administration of clobetasol propionate scalp application during pregnancy and lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. Drugs of this class should not be used extensively in pregnant

patients in large amounts or for prolonged periods of time.

Adverse Reactions

As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercortisolism. Local atrophy may occur after prolonged treatment.

Telangiectasia, dryness of the skin, acneiform eruptions, local burning, irritation, itching, striae, change in pigmentation, secondary infection, hypertrichosis, atrophy of skin and subcutaneous tissue, stinging sensation, scalp pustules, tingling, folliculitis, tightness of the scalp, dermatitis, tenderness, headache, hair loss and eye irritation have been observed following topical corticosteroid therapy. Local adverse events that have been reported infrequently when topical corticosteroids are used as recommended include perioral dermatitis, maceration of the skin and miliaria.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.

In rare instances, treatment of psoriasis with corticosteroids (or their withdrawal) is thought to have provoked the pustular form of the disease.

DERMOVATE® Scalp Application is usually well tolerated, but if signs of hypersensitivity appear, application should be stopped immediately.

Symptoms and Treatment of Overdosage

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be discontinued gradually. However, because of the risk of acute adrenal suppression this should be done under medical supervision.

Dosage and Administration

DERMOVATE® (clobetasol propionate) Scalp Application, 0.05% should be applied once or twice daily to the affected areas of the scalp and rubbed in gently. The total dose applied should not exceed 50 millilitres weekly.

Therapy should be discontinued if no response is noted after one week or as soon as the lesion heals. It is advisable to use DERMOVATE® Scalp Application for brief periods only.

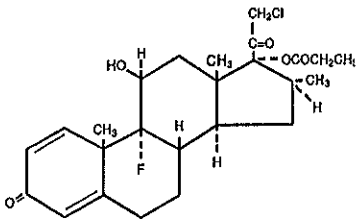
Pharmaceutical Information

Drug Substance

Proper Name: clobetasol propionate (BANM, USAN, INNM)

Chemical Name: 21-chloro-9α-fluoro-11β-hydroxy-16β-methyl-17α-propionyl oxypregna-1, 4-diene-3, 20-dione

Structural Formula:



Molecular Formula: $C_{25}H_{32}C1FO_5$

Molecular Weight: 467

Description: White to cream coloured crystalline powder.

Solubility: Insoluble in water

Melting Point: 195.5 - 197°C

Composition

Each mL of DERMOVATE® (clobetasol propionate) Scalp Application contains 0.05% w/w clobetasol propionate in an aqueous-alcohol base.

Stability and Storage Recommendations

Store below 30°C.

Availability of Dosage Forms

DERMOVATE® (clobetasol propionate) Scalp Application, 0.05% is available in 20 millilitre and 60 millilitre opaque bottles.