

Prescribing Information

EUMOVATE Cream

(clobetasone butyrate, 0.05%)

EUMOVATE Ointment

(clobetasone butyrate, 0.05%)

Topical Corticosteroid

Prescribing Information

EUMOVATE Cream

(clobetasone butyrate, 0.05%)

EUMOVATE Ointment

(clobetasone butyrate, 0.05%)

THERAPEUTIC CLASSIFICATION

Topical corticosteroid

ACTIONS AND 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 clobetasone 17-butyrate 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.

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

Indications and Clinical Use

EUMOVATE (clobetasone butyrate) Cream and Ointment are indicated in the treatment of milder forms of eczema, seborrheic dermatitis, and other corticosteroid-responsive skin conditions, which do not require the use of a more potent topical corticosteroid.

Contraindications

Clobetasone butyrate cream and ointment are not indicated for the treatment of primarily infected skin lesions caused by infection with fungi or bacteria if no anti-infective agent is used simultaneously, primary cutaneous viral infections (i.e., herpes simplex, vaccinia and varicella) or tuberculous skin lesions. Clobetasone butyrate cream and ointment are also contraindicated in patients with a hypersensitivity to any of the components of the preparation.

Warnings

EUMOVATE (clobetasone butyrate) Cream and Ointment should not be used in the eye and should be used with caution in lesions close to the eye as glaucoma may result. Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

If clobetasone butyrate is used under occlusive dressing over extensive areas for prolonged periods, it is possible that sufficient absorption may take place to give rise to transient adrenal suppression. Long-term continuous topical corticosteroid therapy should be avoided where possible as adrenal suppression can occur even without occlusion.

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

Precautions

Significant systemic absorption may result when corticosteroids are applied over large areas of the body. To minimise this possibility, treatment should be interrupted periodically or one area of the body should be treated at a time when long-term therapy is anticipated. In infants, the diaper may act as an occlusive dressing and increase absorption.

As with all corticosteroids, prolonged application of EUMOVATE (clobetasone butyrate) Cream and Ointment to the face is undesirable.

Prolonged or extensive use of topical corticosteroid products may produce atrophy of the skin and subcutaneous tissue, particularly on flexor surfaces and on the face. If this is noted, the use of EUMOVATE should be discontinued.

EUMOVATE should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation.

If a symptomatic response is not noted within a few days to a week, the local application of EUMOVATE should be discontinued and the patient re-evaluated.

In case of bacterial infections of the skin, appropriate anti-bacterial 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.

During the use of topical corticosteroids, secondary infections may occur. Appropriate antimicrobial 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. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

The safety and effectiveness of EUMOVATE when used under occlusive dressings has not been determined.

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

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.

However, the administration of clobetasone butyrate topical preparations 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

When large areas of the body are being treated with EUMOVATE (clobetasone butyrate) Cream or Ointment it is possible that some patients will absorb sufficient steroid to cause transient adrenal suppression despite the low degree of systemic activity associated with clobetasone butyrate.

Local burning, irritation, itching, skin atrophy, dryness of the skin, atrophy of subcutaneous tissues, telangiectasia, striae, change in pigmentation, secondary infection and hypertrichosis have been observed following topical corticosteroid therapy. Exacerbation of symptoms may occur.

Local atrophic changes could possibly occur in situations where moisture increases absorption of clobetasone butyrate, but only after prolonged use.

In the unlikely event of signs of hypersensitivity appearing, application should stop 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 hypercorticism may appear. As with any corticosteroid, treatment should be discontinued if the symptoms of hypercorticism appear.

Dosage and Administration

EUMOVATE (clobetasone butyrate) Cream, 0.05% and Ointment, 0.05% should be applied thinly to cover the affected area, and gently rubbed into the skin.

Frequency of application is two to three times daily according to the severity of the condition.

The total dose of EUMOVATE applied should not exceed 100 grams per week in adults.

Pharmaceutical Information

Drug Substance

Proper Name: clobetasone butyrate (BANM, USAN, rINNM)

Chemical Name: 17 butyryloxy-21-chloro-9 α -fluoro-16 β -methyl-pregna-1,4-diene-3,11,20-trione

Structural Formula:

Molecular Formula: C₂₆H₃₂ClFO₅

Molecular Weight: 479

Description: white to cream colored crystalline powder

Solubility: Clobetasone butyrate is insoluble in water, slightly soluble in ethanol, methanol and diethyl ether, soluble in dioxan and very soluble in toluene, chloroform, ethyl acetate, dimethylsulphoxide and dimethylformamide

Melting Point: 178EC

Composition: Each gram of EUMOVATE Cream contains 0.05% w/w clobetasone butyrate in a cream base.

Each gram of EUMOVATE Ointment contains 0.05% w/w clobetasone butyrate in an ointment base.

Storage Conditions: Store below 30EC.

Availability of Dosage Forms

EUMOVATE (clobetasone butyrate) Cream, 0.05% and Ointment, 0.05% are available in 15 gram and 30 gram tubes.