Clobetasol propionate 0.0525%

Cream

CLOBUTRA

Topical Corticosteroid

Description :

CLO-BUTRA Cream contains the active compound clobetasol propionate, a synthetic corticosteroid, for topical dermatologic use. Clobetasol, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Each gram of **CLO-BUTRA** Cream contains 0.525 mg clobetasol propionate in a cream emollient base.

Clinical pharmacology:

Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic, and vasoconstrictive properties.

Pharmacokinetics:

The extent of percutaneous absorption of topical corticosteroids, including clobetasol propionate, is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings .

As with all topical corticosteroids, clobetasol propionate can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similarly to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids, including clobetasol propionate and its metabolites, are also excreted into the bile.

Clobetasol propionate cream has been shown to depress the plasma levels of adrenal cortical hormones following repeated nonocclusive application to diseased skin in patients with psoriasis and eczematous dermatitis. These effects have been shown to be transient and reversible upon completion of a two-week course of treatment.

Indications and usage:

CLO-BUTRA Cream is a very active topical corticosteroid which is of particular value when used for the treatment of more resistant dermatoses such as:

1- Psoriasis (excluding widespread plaque psoriasis).

2- Recalcitrant eczemas. 3- Lichen planus.

4- Discoid lupus erythematosus.

5- Other skin conditions which do not respond satisfactorily to less active steroids.

Contraindications:

CLO-BUTRA Cream (Clobetasol Propionate Cream) is contraindicated in patients with a history of hypersensitivity to any of the component of the preparation.

Precautions:

As with other potent topical corticosteroids, **CLO-BUTRA** Cream (Clobetasol Propionate Cream) should not be used in the treatment of rosacea and perioral dermatitis. • Not to be used for children less than 12 years old.

If irritation develops, topical corticosteroids should be discontinued and appropriate

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therapy instituted. Should not be used on the face, groin or axillae

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Not to be used for more than 2 consecutive weeks

Not to be used without prescription.

Dose shouldn't exceed 50 gm/week.

Drug interactions:

non reported.

Use during pregnancy and lactation:

In general topical steroids should not be used extensively during pregnancy, i.e. in large amounts for prolonged periods.

The safe use of Clobetasol Propionate during lactation has not been established.

Adverse reactions:

CLO-BUTRA Cream is generally well tolerated when used for two weeks treatment periods.

The most frequent adverse reactions reported to clobetasol propionate cream were burning and stinging sensation in approximately 1% of the patients. Less frequent adverse reactions were itching, skin atrophy, and cracking and fissuring of the skin.

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.

Provided that the weekly dosage is less than 50 gm in adults , any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased.

Prolonged and intensive treatment with highly-active corticosteroids preparations may cause local atrophic changes such as thinning, striae and dilatation of the superficial blood vessels.

In rare instances, treatment (or withdrawal of treatment) of psoriasis with corticosteroids is thought to have provoked the pustular form of the disease, so careful patient supervision is recommended.

Overdosage:

Acute overdosage is very unlikely to occur, however in the case of chronic overdosage, topical steroids should be discontinued gradually.

Dosage and administration:

Apply a thin layer of **CLO-BUTRA** cream to the affected skin areas once or twice daily and rub it gently & completely.

• Therapy should be discontinued when control is achieved.

Presentation:

CLO-BUTRA Cream is supplied in a 10 gm and 25 gm tube.

Store at a temperature not exceeding 30 °C.

Keep out of reach of children.

Manufactured by:

Egyptian Group for Pharmaceutical Industries.

EGPI

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