

BETACLOB CREAM

DESCRIPTION:

White to off white, smooth homogeneous mass

COMPOSITION:

Each gm of the cream contains Clobetasol propionate (Micronised) 0.5mg

ACTIONS & PHARMACOLOGY:

The overall actions of corticosteroids are catabolic. Corticosteroids diffuse across cell membranes and complex with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to D.N.A. (chromatin) and stimulate transcription of messenger R.N.A. (mRNA) and subsequent protein synthesis of various inhibitory enzymes responsible for anti-inflammatory effects of topical corticosteroids. The pharmacologic activity of topical corticosteroids is increased by several changes in molecular structure. Substitution or masking of 16 or 17 - hydroxy groups with longer side chains such as acetonide, propionate or valerate increase lipophilicity and subsequently stratum corneum penetration.

Absorption : Absorbed systemically across the stratum corneum. Stratum corneum penetration is primarily enhanced by increasing skin hydration and or temperature, or by changes in molecular structure of the compound. Hydrating the skin with occlusive dressing such as plastic wrap, a tight-fitting diaper or one covered with plastic pants, plastic tape, or dermatological patches can increase corticosteroid penetration by up to ten-fold. Intertriginous areas and the face also have inherently thinner skin, are more macerated and therefore, allow for increased absorption. Absorption of topical corticosteroids has been greatly increased by altering the product vehicle. Vehicles containing substances that solubilize the corticosteroid enhance absorption. Increasing the concentration of drug increases skin penetration. Decreasing drug particle size has been shown to increase topical bioavailability. Increased percutaneous absorption of corticosteroids also occurs when the skin or mucosa is abraded or inflamed, when body temperature is elevated, with prolonged use, or with extensive use. Biotransformation: Primarily in skin; once absorbed systemically, in the liver. Clobetasol propionate is resistant to local metabolism in the skin. Repeated application results in a cumulative depot effect in the skin, which may lead to a prolonged duration of action, increased side effects, and increased systemic absorption. Excreted by the kidneys and into the bile.

INDICATIONS:

Indicated for short-term treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid responsive dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid, discoid lupus erythematosus and other conditions which do not respond satisfactorily to less active steroids.

CONTRAINDICATIONS:

Rosacea, acne vulgaris and peri-oral dermatitis. Primary cutaneous viral infections (e.g. herpes simplex, chickenpox). Hypersensitivity to corticosteroids. The use of BETACLOB Cream is not indicated in the treatment of primarily infected skin lesions caused by infection

with fungi (e.g. candidiasis, tinea), or bacteria (e.g. impetigo); peri-anal and genital pruritus. Dermatoses in children under one year of age, including dermatitis and napkin eruptions.

SIDE EFFECTS:

The incidence and severity of local or systemic side effects increase with factors that increase percutaneous absorption. Percutaneous absorption has resulted in systemic side effects such as hyperglycemia, glycosuria and hypothalamic-pituitary-adrenal (HPA) axis suppression. Less frequent side effects are burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneform eruptions, pigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

PRECAUTIONS:

Clobetasol propionate is a highly potent topical corticosteroid. BETACLOB cream may be used for only a short duration of therapy and on small surface areas. Occlusive dressings should not be used. Systemic absorption of topical corticosteroids has resulted in reversible HPA axis suppression, manifestations of Cushing's Syndrome, hyperglycemia and glucosuria in some patients. Conditions that augment systemic absorption which include usage over large surface areas, prolonged use, occlusive dressing etc. should be avoided. Patients receiving a large dose applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, withdraw the drug or reduce the frequency of application or substitute to a less potent drug. Children may absorb proportionally larger amounts of topical corticosteroid and may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's Syndrome than mature patients because of a larger skin surface area to body weight ratio. Therefore application of BETACLOB cream to children under 12 years of age is not recommended. Should be used with caution in patients with evidence of pre-existing skin atrophy. 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.

PREGNANCY & LACTATION:

BETACLOB cream should not be used extensively, in large amounts, or for prolonged periods in pregnant patients. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animal can cause abnormalities of fetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human fetus. It is not known whether topical corticosteroids are distributed into breast milk. However, problems in humans have not been documented. Topical corticosteroids should not be applied to the breasts prior to nursing.

DRUG INTERACTION: No drug interactions are reported.

DOSAGE & ADMINISTRATION:

Apply with gentle rubbing to the affected skin areas two or three times a day. Usage is not recommended for children up to 12 years of age. Do not use in or around eye.

As with other highly-active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.

ROUTE OF ADMINISTRATION:

Topical administration

OVERDOSAGE & TREATMENT:

Symptoms: Acute overdose is very unlikely to occur.

Treatment: Since there is no specific antidote available, treatment is symptomatic, supportive and consists of discontinuance of topical corticosteroid therapy. If a local infection develops at the site of application, discontinue the therapy and institute appropriate antimicrobial therapy.

PRESENTATION:

Aluminium tubes of 5g, 10g and 15g

STORAGE:

Store in a cool dry place below 30 °C.

Keep containers tightly closed.

Protect from light and freezing.

Keep medicine out of reach of children.

For external use only.

MANUFACTURED BY:

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