

CLOBUTRATE CREAM 0.05% W/W

NAME AND STRENGTH OF ACTIVE INGREDIENT(S):

Clobetasone Butyrate 0.05% w/w

PRODUCT DESCRIPTION:

Clobutrate Cream 0.05% w/w : A smooth white cream in aluminium tubes with white caps.

PHARMACODYNAMICS:**Mechanism of action**

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the mechanism of arachidonic acid.

Pharmacodynamic effects

Topical corticosteroids have anti-inflammatory, antipruritic and vasoconstrictive properties.

PHARMACOKINETICS:**Absorption**

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

COMPOSITION:

Clobetasone Butyrate 0.05% w/w: Each gram of cream contains 0.5mg of Clobetasone Butyrate

INDICATION:

Clobutrate Cream is a moderately potent topical corticosteroid indicated for adults, elderly, children and infants for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses.

These include the following:

- Atopic dermatitis
- Irritant or allergic contact dermatitis
- Seborrhoeic dermatitis
- Nappy rash
- Photodermatitis
- Otitis externa
- Prurigo nodularis
- Insect bite reactions

Clobutrate Cream may be used as maintenance therapy between courses of one of the more potent topical steroids.

ROUTE OF ADMINISTRATION:

External, locally applied.

RECOMMENDED DOSAGE:

Apply to the affected area up to four times daily until improvement is seen; then reduce frequency of application.

CONTRAINDICATIONS:

Hypersensitivity to Clobetasone Butyrate, or to any ingredient in this preparation. The use of Clobutrate Cream 0.05% w/w is not indicated for untreated cutaneous infections, rosacea, acne vulgaris and pruritus without inflammation.

WARNINGS AND PRECAUTIONS:

- Caution should be taken for patients with a history of local hypersensitivity to other corticosteroids.
- Cushing's syndrome and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression leading to glucocorticosteroid insufficiency can occur due to increased systemic absorption of topical steroids. If any of the above are observed, withdraw the product gradually by reducing the frequency of application or substituting to a less potent corticosteroid.
- Clobutrate Cream 0.05% w/w contains cetostearyl alcohol which may cause local skin reactions and chlorocresol which may cause allergic reactions.
- The risk factors that increase systemic effects including:
 - potency and formulation of topical steroid
 - duration of exposure
 - application to a large surface area
 - application on occluded areas of skin or under occlusive dressing (e.g. napkin used in infant can be considered as an occlusive dressing).
 - Increasing hydration of the stratum corneum.
 - Use on thin skin areas such as the face.
 - Use on broken skin or impaired skin barrier.
- Paediatric population:
 - Children and infants may absorb proportionally larger amounts of corticosteroids because of their higher surface area to body mass ratio. Thus, they are more likely to develop systemic adverse reactions. A shorter treatment is recommended.
 - Long term topical corticosteroid application should be avoided for infants and children under 12 years of age as adrenal and growth suppression is more likely to occur.
- Infection risk with occlusion:
 - The skin should be cleaned first before using occlusive dressing. This is to reduce the risk of bacteria infection caused by the warm, moist conditions within skin folds or caused by occlusive dressing.
- Avoid prolonged application to the face as this area is more susceptible to atrophic changes.
- Caution should be taken during the application to the eyelids. The preparation must not enter the eye as cataract and glaucoma might result from repeated exposure.
- 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 treatment of appropriate antimicrobial therapy by your doctor.
- Topical corticosteroids used to treat the dermatitis around chronic leg ulcers may increase the risk of local hypersensitivity reactions and local infection.
- Clobutrate Cream 0.05% w/w is strictly for external use only. It should be kept out of reach of children. In case of accidental ingestion, you must consult to a doctor immediately.

INTERACTIONS WITH OTHER MEDICAMENTS:

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent of this interaction depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

PREGNANCY AND LACTATION:

Pregnancy

Safety of its use during pregnancy has not been established. The administration of clobetasone during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. Women who are pregnant should consult a doctor before use. The minimum quantity should be used for the minimum duration.

Lactation

The safe of its use during lactation has not been established. Administration of clobetasone during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation, clobetasone should not be applied to the breasts to avoid accidental ingestion by the infant.

SIDE EFFECTS:

- Opportunistic infection.
- Immune System Disorders such as hypersensitivity, generalised rash.
- Endocrine Disorders such as Hypothalamic-pituitary adrenal (HPA) axis suppression, cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children. , osteoporosis, glaucoma, cataract, hyperlycaemia/glucosuria, hypertension, increased weight/obesity, decreased endogenous cortisol levels.
- Skin and Subcutaneous Tissue Disorders such as allergic contact dermatitis, urticaria, skin atrophy, pigmentation changes, exacerbation of underlying symptoms, local skin burning, hypertrichosis, rash, pruritus, erythema.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Corticosteroid applied to the skin can be absorbed in sufficient amount to produce systemic effect. The features of hypercortisolism may occur in the case of chronic overdosage or misuse. In the case of overdosage, clobetasone should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE

No studies on the effects on the ability to drive and use machines have been performed.

PRECLINICAL SAFETY DATA

Not applicable

INSTRUCTION FOR USE

For external use only.

STORAGE CONDITIONS

Store in the original package and in a dry place.

Do not store above 30°C.

Keep out of reach of children

DOSAGE FORMS AND PACKAGING AVAILABLE:

Dosage form : Cream

Aluminium tube : 50 x 15g

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,

Pulau Pinang, Malaysia.

DATE OF REVISION:

23/11/2017