CLODERMA

(Clobetasol Cream BP)

COMPOSITION:

Each gm contains:

Clobetasol Propionate	BP	0.05% w/w
Cream Base		q.s.
Preservatives :		
Methylparaben	BP	0.15%w/w
Propylparaben	BP	0.05%w/w

PHARMACODYNAMIC:

Pharmacotherapeutic group: Corticosteroids, very potent
ATC code: D07AD

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 metabolism of arachidonic acid.

Pharmacodynamic effects

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

PHARMACOKINETIC:

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.

INDICATION:

Clobetasol is a very potent topical corticosteroid indicated for adults, elderly and children over 1 year for the short term treatment only of more resistant inflammatory and pruritic manifestations of steroid responsive dermatoses unresponsive to less potent corticosteroids. These include the following:

- Psoriasis (excluding widespread plaque psoriasis)
- Recalcitrant dermatoses
- Lichen planus
- Discoid lupus erythematosus
- Other skin conditions which do not respond satisfactorily to less potent steroids.

POSOLOGY AND METHOD OF ADMINISTRATION:

Route of administration: Cutaneous

Creams are especially appropriate for moist or weeping surfaces.

Adults, Elderly and Children over 1 year

Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day until improvement occurs (in the more responsive conditions this may be within a few days), then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient.

Repeated short courses of clobetasol propionate may be used to control exacerbations.

In more resistant lesions, especially where there is hyperkeratosis, the effect of clobetasol can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.

Treatment should not be continued for more than 4 weeks. If continuous treatment is necessary, a less potent preparation should be used.

The maximum weekly dose should not exceed 50gms/week.

Therapy with clobetasol should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy.

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of clobetasol.

SPECIAL WARNING AND PRECAUTION FOR USE:

Clobetasol should be used with caution in patients with a history of local hypersensitivity to other corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions (*see section 4.8*) may resemble symptoms of the condition under treatment.

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency.

Risk factors for increased systemic effects are:

Potency and formulation of topical steroid

Duration of exposure

Application to a large surface area

Use on occluded areas of skin (e.g. on intertriginous areas or under occlusive dressings(in infants the nappy may act as an occlusive dressing)

Increasing hydration of the stratum corneum

Use on thin skin areas such as the face

Use on broken skin or other conditions where the skin barrier may be impaired

In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Paediatric population

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur

Children are more susceptible to develop atrophic changes with the use of topical corticosteroids.

Duration of treatment for children and infants

Courses should be limited if possible to five days and reviewed weekly. Occlusion should not be used.

Infection risk with occlusion

Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied.

Use in Psoriasis

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

Concomitant infection

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 administration of appropriate antimicrobial therapy.

Chronic leg ulcers

Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Application to the face

Application to the face is undesirable as this area is more susceptible to atrophic changes.

If used on the face, treatment should be limited to 5 days.

Application to the eyelids

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure. If clobetasol does enter the eye, the affected eye should be bathed in copious amounts of water.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

CONTRAINDICATION:

Hypersensitivity to the active substance or any of the excipients.

The following conditions should not be treated with Cloderma:

Untreated cutaneous infections

Rosacea

Acne vulgaris

Pruritus without inflammation

Perianal and genital pruritus

Perioral dermatitis.

Clobetasol is contraindicated in dermatoses in children under one year of age, including dermatitis and nappy eruptions

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

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

PREGNACY AND LACTATION:

Pregnancy

There are limited data from the use of clobetasol in pregnant women.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development

The relevance of this finding to humans has not been established. Administration of clobetasol during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Breast-feeding

The safe use of topical corticosteroids during lactation has not been established.

It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of clobetasol during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation clobetasol should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility

There are no data in humans to evaluate the effect of topical corticosteroids on fertility

Clobetasol administered subcutaneously to rats had no effect upon mating performance; however, fertility was decreased at the highest dose

ADVERSE REACTION:

Commonly reported side effects include:

- Burning, irritation, and itching of the skin where you applied the drug

Serious side effects

Serious side effects and their symptoms can include the following:

- Adrenal insufficiency. Symptoms can include:
  - low blood pressure
  - fainting
  - dizziness
  - tiredness
  - Cushing's syndrome. Symptoms can include:
  - high blood sugar or blood sugar in your urine, with symptoms such as:
  - urinating more often than normal
  - intense thirst
  - intense hunger
  - high blood pressure

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

There have been no studies to investigate the effect of clobetasol on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical clobetasol.

OVERDOSE:

Symptoms

Topically applied clobetasol may be absorbed in sufficient amounts to produce systemic effects. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may occur.

Management

In the event of overdose, clobetasol should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency.

INCOMPATIBILITY:

Not applicable

SHELF LIFE:

36 months

PACKAGING:

30 gm laminated tube packed in a carton along with pack insert.

STORAGE CONDITION:

Store in a dry place below 30^0C. Protect from light.

FABRIQUE PAR :

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DISTRIBUE ET COMMERCIALISE PAR :

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