CLOBESOL OINTMENT 0.05% W/W

NAME AND STRENGTH OF ACTIVE INGRDIENT(S):
Clobetasol Propionate 0.05% w/w

PRODUCT DESCIPTION:
A semi-transparent, unctuous off -white ointment 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 metabolism 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.

INDICATION:
Clobetasol propionate is a very active topical corticosteroid which is of particular value when used in short courses for the treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas lichen planus, discoid lupus erythematosus, and other conditions which do not respond satisfactorily to less active steroids.

RECOMMENDED DOSAGE:
Apply gently to the affected area once or twice daily until improvement occurs. Treatment with topical corticosteroid should be discontinued once control is achieved. It is recommended that the treatment should not exceed four weeks without the patient's condition being reviewed. However, repeated short treatments of Clobesol Ointment may be used to control exacerbations. If a continuous treatment is required, a less potent preparation should be used. For a more resistant lesion, especially where there is hyperkeratosis, the anti-inflammatory effect of Clobesol Ointment can be enchanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion is usually adequate to bring out a satisfactory result. Subsequently the condition can be maintained by application without occlusion.

ROUTE OF ADMINISTRATION:
External, locally applied.

CONTRAINDICATIONS:
Hypersensitivity to the preparation or patients with the following conditions should not be treated with Clobesol:
- Untreated cutaneous infections caused by fungi or bacteria
- Rosacea
- Acne vulgaris

- Pruritus without inflammation
- Perianal and genital pruritus
- Perioral dermatitis
- Dermatoses in children under one year of age, including dermatitis and nappy eruptions.
- Primary cutaneuos viral infection (e.g. herpex simplex, chickenpox)

WARNINGS AND PRECAUTIONS :

- Paediatric population:
  - Avoid long term continuous application with Clobesol Ointment, particularly in children and infants as adrenal suppression might occur.
  - If used in children, it is recommended that the therapy should be reviewed weekly, so that the least potent corticosteroid which will control the disease can be selected.
  - In infants, the napkin may act as an occlusive dressing.
- The face may exhibit atrophic changes after prolonged therapy with potent topical corticosteroids. Caution must be taken when treating psoriasis, discoid lupus erythematosus and severe eczema.
- Caution should be taken during the application to the eyelids. The preparation must not enter the eye as glaucoma might result.
- 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.
- If an occlusive dressing is applied, the skin should be cleaned first as the bacterial infection is encouraged by the warm, moist conditions within skin folds.
- Caution with the use of topical corticosteroids in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity might occur due to impaired barrier function of the skin .
- If used in psoriasis, careful patient supervision must be taken.
- Topical corticosteroid should not be used in large amounts or for prolonged periods in pregnancy.

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

The safe use of Clobetasol propionate during pregnancy has not been established in pregnant women. Topical corticosteroids should only be considered if the expected benefit to the mother outweighs the risk of the foetus. Women who are pregnant should consult a doctor before use.

Lactation

The safe of its use during lactation has not been established. It is not known whether topical corticosteroids are distributed into milk. They should be used with caution in nursing women. If used during lactation, Clobesol Ointment should not be applied to the breasts to avoid accidental ingestion by the infant. Women who are breast-feeding should seek medical advice before using this product.

SIDE EFFECTS:

Immune system disorders

Very rare : Hypersensitivity

Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria, local skin burning and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment.

If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders

Very rare: Features of Hypercortisolism

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. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the napkin may act as an occlusive dressing.

Provided the weekly dosage is less than 50g in adults, any suppression of the Hypothalamic-pituitary adrenal (HPA) axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased.

Vascular disorders

Uncommon : Dilatation of the superficial blood vessels.

Prolonged and intensive treatment with highly-active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used; or when skin folds are involved.

Skin and subcutaneous tissue disorders
Uncommon: Local atrophy, striae
Very rare: Thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis.
Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae, particularly when occlusive dressings are used, or when skin folds are involved.
In very rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Acute overdosage is unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercortisolism may appear.
In this situation topical steroids should be reduced or discontinued gradually under medical supervision because of the risk of adrenal insufficiency.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:

There have been no studies to investigate the effect of Clobetasol Propionate on driving performance or the ability to operate machinery.

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 30ºC.
Keep out of reach of children.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Dosage Form ***:*** Ointment
Packing Size ***:*** 1x15g (aluminium tube), 50x15g (aluminium tubes)

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