of methylprednisolone and possibly other corticosteroids; itraconazole possibly inhibits metabolism of methylprednisolone.

Symptoms and Treatment of Overdose:
No overdosage symptoms occur except on excessive use of steroid cream may cause systemic absorption that may result in adrenal suppresion.

Storage Condition:

Keep container tightly closed. Store in a dry place (below 30^{O}C). Protect from light.

Pack Size:
Plastic jar containing 500g of cream.
Aluminium tube containing 10g, 15g and 30g of cream.

Products Registration Number:
MAL19870604AZ

Further information can be obtained from your doctor or pharmacist.

ROYCE®

Product Registration Holder / Manufactured by:
ROYCE PHARMA MFG. SDN.BHD. (650435-X)
PT 1663, Nilai Industrial Estate,
71800 Nilai, Negeri Sembilan Darul Khusus, Malaysia.

Revision date:13122

ROYCE®

Royce Betasone Cream 0.1% w/w

(Betamethasone Valerate – Topical Corticosteroid)

Presentation :
A white colour, smooth cream.

Contents:
Betamethasone (17-Valerate) 0.1%w/w

Preservatives:
Methyl Paraben 0.15%w/w
Propyl Paraben 0.08%w/w

Pharmacological Information:
Betamethasone 17 Valerate is an topical corticosteroid and is a very active anti-inflammatory agent. Bethamethasone 17 Valerate produces a rapid response in those inflammatory dermatoses such as eczemas. Betamethasone is a synthetic glucocorticoid and has the general properties as Corticosteroids. When administrated by topical application, particularly under an occlusive dressing or when the skin is broken. Sufficient steroid may be absorbed to give systemic effects. Betamethasone valerate is absorbed through the skin when applied topically. It is metabolized mainly in the liver but also in the kidney, and is excreted in the urine.

Indication:
Betamethasone valerate is an active topical corticosteroid which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy. Betasone is indicated for the treatment of: eczema, including atopic, infantile and discoid eczemas, prurigo, psoriasis, neurodermatoses, including lichen simplex, lichen planus, seborrhoeic dermatitis, intertrigo, contact sensitivity reactions, discoid lupus erythematosus and may be used as an adjunct to systemic steroid therapy in generalised erythroderma.

Dosage and Administration:
For external use only
A small quantity of Betasone should be applied to the effected area 1 to 3 times daily until improvement occurs. Betasone Cream is especially appropriate for moist or weeping surfaces. In the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effect of Betasone can be enhanced, if necessary, by occluding the treatment area with polyethylene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions; thereafter improvement can usually be maintained by regular applications with occlusion.
Use in children:
Use smallest amount for effective treatment. Children may be more susceptible than adults to HPA axis suppression and Cushing's syndrome because of the larger ratio of surface area to body weight, interacranial hypertension has also been observed in children receiving topical corticosteroids. Chronic therapy may interfere with growth and development.

Contraindication:
Rosacea, acne and peri-oral dermatitis.Skin lesions caused by infection with viruses (e.g herpes simplex, chickenpox), fungi (e.g. candidiasis; tinea) or bacteria (e.g.impetigo).

Warning and Precaution:
Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppresion can occur even without occlusion. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mild lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does 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 to topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressing, and the skin should be cleansed before a fresh dressing is applied. If there is irration, discontinue use institute appropriate therapy.

Pregnancy and Lactation:
Pregnancy:
Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development. The relevance of this finding to human beings has not been established; however, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

Nursing Mothers:
It is not known whether topical corticosteroids are excreted in human milk. Although systemic corticosteroids are excreted in quantities unlikely to harm nursing infants, this preparation should be used with caution in nursing mothers.

Side Effects:
Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as striae, thinning and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved.

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 hypercorticism. The effect is more likely to occur in infants and children, and if occlusive dressings.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular from the disease. If signs of hypersensitivity appear, application should stop immediately.

Interactions With Other Medicaments:
Betamethasone valerate is an active topical costicosteriod which produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy and is often effective in the less responsive conditions. E.g. psoriasis.

Antifungals: increased risk of hypokalaemia with amphotericin (avoid concomitant use unless corticosteriods required to control reactions); ketoconazole inhibits metabolism