Storage condition:
Keep container tightly closed. Store in a dry place (below 30°C). Protect from light.

Pack Size:
i) 15g & 100g in an aluminium tube.
ii) 450g of cream in a plastic jar (for tender only).

Registration Number:
MAL19870461AZ

Further information can be obtained from your doctor or pharmacist.

ROYCE®

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

Revision Date: 290917

ROYCE®

Hydrocortisone Acetate Cream 1% w/w

(Hydrocortisone Acetate- Topical Corticosteroid)

Presentation:
A white colour, smooth cream.

Content:
Hydrocortisone Acetate 1% w/w

Preservatives:
Methylparaben 0.08% w/w
Propylparaben 0.15% w/w

Pharmacological Information:
Following topical application, hydrocortisone produce anti-inflammatory, antipruritic and vasoconstrictor actions. The activity of the drugs is thought to result at least in part from binding with a steroid receptor. Hydrocortisone decrease inflammatory by stabilizing leukocyte lysosomal membranes, preventing release of destructive acid hydrolyses from leukocytes; inhibiting macrophage accumulation in inflamed areas; reducing leukocyte adhesion to capillary endothelium; reducing capillary wall permeability and edema formation; decreasing complement components; antagonizing histamine activity and release of kinin from substrates; reducing fibroblast proliferation, collagen deposition and subsequent scar tissue formation.

Percutaneous penetration of hydrocortisone varies among individual patients and can be increased by the use of occlusive dressings, by increasing the concentration of the hydrocortisone and by using different vehicles. Following topical application of a hydrocortisone to most areas of normal skin only minimal amounts of the drug reach the dermis and subsequently the systemic circulation, however absorption is markedly increased when the skin has lost its keratin layer.

The drugs are absorbed to a greater degree from the scrotum, axilla, face and scalp than from the scrotum, axillia, cyclid, face and scalp than from the forearm, knee, elbow, palm, and sole. Even after washing the area being treated, prolonged absorption of the hydrocortisone occurs, possibly because the drug is retained in the stratum corneum.

Indication:
Hydrocortisone has topical anti-inflammatory activity of value in the treatment of a wide variety of dermatological conditions, including the following: eczema, including atopic, infantile, discoid and stasis eczemas: prurigo, neurodermatoses, including lichen simplex, seborrhoeic dermatitis, intertrigo, contact sensitivity reactions; discoid lupus erythematosus, generalised erythroderma.

Dosage and administration:
A small quantity should be applied to the affected area two or three times daily. Hydrocortisone Acetate Cream is often appropriate for moist or weeping surfaces.

Use in children:
Use smallest amount necessary 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; intracranial hypertension has also been observed in children receiving tropical corticosteroids. Chronic therapy may interfere with growth and development.

Contraindications:
Skin lesions caused by infection with viruses (e.g herpes simplex, chickenpox), fungi (e.g candidiasis, tinea) or bacteria (e.g impetigo). Hypersensitivity to the preparations.

Warning and Precautions:
Not to let this preparation come into contact with patient's eyes. If an occlusive dressing is not indicated, caution patients not to bandage or otherwise cover the treated area so that it becomes occluded (this tight-fitting diapers or plastic pants should not be used on children being treated in the diaper area).

Dermatological infection - Discontinue use of any occlusive dressings and institute appropriate antifungal or antibacterial therapy; if infection persists; discontinue steroid absorption. Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia and glucosuria may result from systemic absorption after topical application, particularly in children (see DOSAGE & ADMINISTRATION). Use over extensive areas, for prolonged periods, or of occlusive dressings increases percutaneous absorption.

Pregnancy:
Use during pregnancy only if the expected benefit justifies the potential risk to the fetus. Do not use over extensive areas, in large amounts or for prolonged periods.

Nursing mothers:
It is 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:
Local-burning, itching, irritation,dryness, olliculitis, hypertrichosis, acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration, secondary infection, skin atrophy, striae, miliaria. Local atrophic changes may occur where skin folds are involved, or in areas such as the nappy area in small children, where constant moist conditions favour the absorption of hydrocortisone. Sufficient systemic absorption may also occur in such sites to produce the features of hypercorticism after prolonged treatment. This effect is more likely to occur in infants and children, and if occlusive dressings are used. If signs of hypersensitivity appear, application should stop immediately.

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