YSP HYDROCORT CREAM 1% W/W

Ingredient(s):
Each gram contains:
Hydrocortisone Acetate ……..…… 10mg

Excipients:
Butylated Hydroxyanisole, Butylated Hydroxytoluene, Stearic Acid, Bees Wax, Cetyl Alcohol, Dimethylpolysiloxane, Mineral Oil, Propyl Paraben, Methyl Paraben, Glyceryl Monostearate, Propylene Glycol, Polysorbate 80, Triethanolamine, Xanthan Gum, Hydroxyethyl Cellulose, Purified Water.

Description:
A white to off-white color cream.

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):
YSP Hydrocort Cream 1% w/w contains Hydrocortisone Acetate 1%, a glucocorticoid which has anti-inflammatory, antipruritic and vasoconstrictive action. It is effective in the treatment of various skin disorders without causing major adverse reaction compare to other more potent corticosteroid.
YSP Hydrocort Cream 1% w/w increase the water binding capacity of the stratum corneum. It combined with an emollient base that helps to retain existing skin moisture and maintains the skin in a soft and supple conditions.
YSP Hydrocort Cream 1% w/w can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption of YSP Hydrocort Cream 1% w/w.
Once absorbed through the skin, hydrocortisone is handled through pharmacokinetic pathways similar to systemically administered hydrocortisone. It is metabolized primarily in the liver and are then excreted by the kidney.

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Indication(s):
Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Dosage and Administration:
A small amount should be applied topically, twice daily.
To be used as directed by the physician.

Contraindication(s):
1. Contraindicated in patients who have shown hypersensitivity to this drug.
2. Contraindicated in primary bacterial, viral and fungal diseases of the skin and secondarily infected eczemas or intertrigo.

Side effect(s) / Adverse Reaction(s):
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. They are burning, irritation, itching, dryness, folliculitis, hypertrichosis acneiform eruption, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.
Eye disorders: Vision, blurred

Precaution(s) / Warning(s):
1. Avoid contact with eyes. Discontinue use if irritation or rash occur. Should not be used in weeping surfaces. Caution should be exercised when using in children. In infants or children, long term continuous therapy should be avoided. Prolonged

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application to the face is undesirable.

2. Systemic or local therapy which may increase the risk of serious or fatal infection in individuals exposed to viral illnesses such as chickenpox or measles.
3. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, glucosuria in some patients. This include the application of more potent steroids, use over large surface area, prolonged use and the use of occlusive dressing.
4. If local irritation develops following topical corticosteroid use, the product should be discontinued.
5. There are no adequate & well-controlled studies in pregnant women on teratogenic effect from topically applied corticosteroid. Therefore, topical corticosteroid should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Corticosteroid is excreted into breast milk when administered systemically. However, it is not known whether topical administration could result in detectable quantities in breast milk. Nevertheless, caution should be exercised when topical corticosteroid are administered to a nursing woman.
6. 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.

Drug Interactions:
None have been mentioned.

Symptoms and Treatment for Overdosage and Antidote(s):
No any significantly toxic reaction in man by topical application.

Shelf-life:
3 years from the date of manufacture.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30ºC. Protect from light and moisture.

Packing(s):
Aluminium tube of 10g / 20g.
Plastic jar of 500g.
(Not all presentations may be available locally)

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Y. S. P.®

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan, Malaysia.

Product Registrant and Importer:
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