HYDROCORTISONE CREAM

Composition: Hydrocortisone Acetate 1.0% w/w

Pharmacology:
Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity of topical corticosteroids is unclear. However, there is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man. The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.
Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

Indications:
It is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Dosage:
A thin film of the cream is applied to be affected skin areas one to three times a day. Dosage of once or twice a day is often effective.

Side-effects:
The following local adverse reactions have been reported with topical dermatologic corticosteroids, especially under occlusive dressings; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

Contraindications:
It is contraindicated in patients who are hypersensitive to hydrocortisone or to any of the components of the preparation.

Precautions/Warnings:
Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glycosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.
Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroidRecovery of HPA axis function is generally prompt and complete upon discontinuation of the drug..

Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or anti-bacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches and bilateral papilledema.
Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroids therapy may interfere with the growth and development of children.

Use In Pregnancy and Lactation:
Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

Drug Interactions:
No known drug interaction.

Symptoms and Treatment for overdosage and antidote(s):
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effect. (See Precautions / Warnings)

Pack size: A tube of 15g and 30g
A box of 50 x 15g / tube
A jar of 400g and 450g
Pack size : A jar of 500g **(**for hospital and skin specialist clinic use**)**

Storage conditions: Store at or below 30ºC. **Shelf-life:** 3 years.

Description: A white and smooth cream.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer:
Sunward Pharmaceutical Sdn. Bhd.
No. 9 ,11&17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

EL210A-R11
Revised Date : 28/04/2017

and