desonide
Desowen® 0.05% (0.5mg/g)

CORTICOSTEROID

Formulation:
Each gram of Desowen Cream contains 0.5 mg of desonide microdispersed in a compatible vehicle buffered to the pH range of normal skin. It contains Potassium sorbate, Polysorbate 60, Sorbic acid, Propyl gallate, Wax SE, Beeswax synthetic, Stearic acid, Isopropyl palmitate, Propylene glycol, Sodium hydroxide solution, Citric acid anhydrous solution and Purified water.
Each gram of Desowen Lotion contains 0.5 mg of desonide in a lotion vehicle consisting of Tetrasodium EDTA tetrahydrate, Methyl parahydroxybenzoate, Sodium lauryl sulfate, Liquid paraffin 15-25 mPa.s, Glyceryl monostearate SE, Sorbitan monostearate, Cetyl alcohol, Stearyl alcohol, Propyl parahydroxybenzoate, Propylene glycol, Sodium hydroxide solution, Citric acid anhydrous solution and Purified water.

Clinical Pharmacology:
Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions.
The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics:
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. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see Dosage and Administration).
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 similar metabolites are also excreted into the bile.

Indication:
Desonide (Desowen) Cream 0.05% and Lotion 0.05% are indicated for the relief of the inflammatory and pruritic manifestation of corticosteroid-responsive dermatoses.

Contraindication:
Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any components of the preparations.

Precautions:
General systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (PA) axis suppression manifestations of Cushing's syndrome, hyperglycemia and glucosuria 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 steroid.
Recovery 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.
Children may absorb proportionally large amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (See Precautions – Pediatric Use).
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 antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.
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.

Information for the Patient:
Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Galderma Laboratories

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GALDERMA

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DIELINES

Pregnancy Category C:
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well controlled studies in pregnant women in teratogenic effects from topically applied corticosteroids. Therefore, 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.

Nursing Mothers:
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use:
Pediatric patients may demonstrate a 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 of fontanelles, headaches and bilateral papilledema.
Administration of topical corticosteroids to children should be limited to the least amount of compatibility with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

Adverse Reaction:
The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence - burning, itching, irritation, dryness, folliculitism hypertrichosis, acneiform eruptions, hypopigmentation, perioral dematitis, allergic contact dermatitis, maceration of the skin secondary infection, skin atrophy, striae, miliaria, blurred vision.

Overdosage:
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (See Precautions).

Dosage and Administration:
Desonide (Desowen) Cream 0.05% or Lotion 0.05% should be applied to the affected areas as a thin film two or three times daily depending on the severity of the condition.
Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions or as prescribed by a physician. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

Availability:
Desonide (Desowen) Cream 0.05%, in 15 g tube
Desonide (Desowen) Lotion 0.05%, in 60 mL bottle

Storage Condition:
Store at a temperature not exceeding 30°C.

Caution:
Food, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Manufactured by:
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