DENSID™
(Desonide)

Cream 0.05% w/w / Ointment 0.05% w/w

10g

ڈینسڈ
(ڈیسونائیڈ)

کریم
آئنٹمنٹ

۱۰ گرام

QUALITATIVE AND QUANTITATIVE DESCRIPTION

DENSID™ Ointment 0.05% w/w
Each gram contains:
Desonide U.S.P. ……0.5mg
Innovator's Specifications

DENSID™ Cream 0.05% w/w
Each gram contains:
Desonide U.S.P. ……0.5mg
Innovator's Specifications

DESCRIPTION:

DENSID™ is an anti-inflammatory and antipruritic corticosteroid designed for topical use in inflammatory dermatoses.

CLINICAL PHARMACOLOGY

Human dose titration studies were carried out using two different methods, both in a double-blind randomized fashion with fluocinolone acetonide 0.025% as the reference steroid. In the first method, patients with symmetrical bilateral skin lesions were selected. In the second method, ambulatory or hospitalized patients afflicted with stabilized psoriasis were employed. In the former investigation desonide 0.025% cream was found equipotent with fluocinolone acetonide 0.025%. However, using the sign test at a significant level of $\alpha=0.05$, the same concentration of desonide was shown to be superior ($p<0.03$) to fluocinolone acetonide 0.025% on first week objective evaluation. The second investigation yielded similar results. Human systemic effects studies were carried out with desonide cream 0.02% in parallel with fluocinolone acetonide cream 0.01% on patients with 10%, 30%, 60%, and 90% of the body surface treated and occluded for one week in a double-blind design. All of the patients had dermatoses responsive to corticosteroid preparations, primarily psoriasis or exfoliative dermatitis, but a rare patient was included who had an eczematous dermatitis. The patients were divided into groups of six according to body surface involvement with random assignment to the steroids under investigation. Testing for suppression of the pituitary-adrenal axis with metapyrone before and just after treatment revealed unequivocal suppression in one patient in the desonide group with 60% body surface involvement. In the same group another patient exhibited mild adrenal suppression. In contrast, in the fluocinolone acetonide group with 60% body surface involvement, two patients showed unequivocal adrenal suppression. In the 90% body surface group both steroids caused unequivocal adrenal suppression for one patient each. Blood chemistry (haemoglobin, haematocrit, red and white cell counts with differential, fasting blood sugar), hepatic function tests (alkaline phosphatase, SGOT and SGPT) and renal function tests (BUN and complete urinalysis) were investigated before and after 4 weeks treatment with desonide or fluocinolone acetonide in 204 patients ranging in age from 2 to 84 years. One patient treated with desonide had a slightly elevated post-treatment fasting blood sugar, and three showed slight elevations in their post-treatment SGOT levels. Both laboratory alterations were equally and more frequently observed following treatment with fluocinolone acetonide. In all probability, these laboratory alterations following either topical steroid are not drug-related but appeared to be intrinsic to the clinical population.

INDICATIONS AND USAGE

DESONIDE 0.05% w/w topical preparations are intended for use in the management

of acute or chronic dermatoses. They have been demonstrated to have anti- inflammatory activity
when used topically in:
- Atopic Dermatitis
- Contact Dermatitis (including Poison Ivy and Venenata)
- Psoriasis
- Eczema (including Nummular Eczema)
- Neurodermatitis
- Seborrheic Dermatitis
- Lichen Simplex Chronicus (Lichen Planus)
- Dyshidrosis
- Acute Solar Dermatitis (Sunburn)
- Statis Dermatitis

DOSAGE AND ADMINISTRATION:

A thin layer of desonide 0.05% w/w Cream or Ointment should be applied to the affected skin thoroughly covering the area. The usual dosage is two to three times daily; however, this may be increased in the treatment of refractory cases.

CONTRAINDICATIONS:

As with all topical corticosteroids, desonide should not be used in untreated bacterial, tubercular and fungal infections of the skin or in viral infections with skin lesions, including herpes simplex, vaccinia and varicella. It is also contraindicated in individuals with history of hypersensitivity to its components.

Other Adverse Reactions:

Side effects have been rare and consist mainly of local burning irritation and itching. When this occurs, the possibility of sensitization must be kept in mind. Because skin atrophy, striae, hypertrichosis and adrenal suppression have been shown to occur with prolonged and indiscriminate use of topical corticosteroids, particularly under occlusion, due to percutaneous absorption, similar phenomena could conceivably occur with prolonged and excessive use of desonide. Folliculitis, acne form eruptions, dryness of skin, maceration of skin and hypo-pigmentation have been shown to occur with the use of topical corticosteroids, and could presumably appear with the use of desonide. Allergic contact dermatitis has been reported following the use of products containing methylparaben, which is present in pdp-DESONIDE cream as a preservative. Posterior subcapsular cataracts have been reported following the systematic use of corticosteroids.
Treatment of Accidental Ingestion:
There is no specific antidote but gastric lavage should be performed.

Special warnings and precautions for use

WARNINGS:

• The safety of topical corticosteroids during pregnancy or lactation has not been established. The potential benefit of topical corticosteroids, if used during pregnancy or lactation, should be weighed against possible hazard to the fetus or the nursing infant.
• If used under an occlusive dressing, particularly over extensive areas, sufficient absorption may take place to give rise to adrenal suppression and other systematic effects.
• Topical corticosteroids are not for ophthalmic use.

PRECAUTIONS:

Although side effects are not ordinarily encountered with topically-applied corticosteroids, as with all drugs, a few patients may react unfavourably under certain conditions. Should sensitivity or idiosyncratic reactions occur, the agent should be discontinued and appropriate steps taken. Topical steroids should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time. Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

Causal factors should be eliminated whenever possible. It is recommended that rotation of the sites of application and intermittent therapy be considered. Suitable precautions should be taken in using topical corticosteroids in patients with statis dermatitis and other skin diseases with impaired circulation. Prolonged use of corticosteroid-containing products, particularly when applied under occlusive dressings, may produce striae or atrophy of the skin or subcutaneous tissue, in which event treatment with such products should be discontinued. In case of bacterial infection of the skin, appropriate anti-bacterial agents should be used as primary 6 therapy. If it is considered necessary, the topical corticosteroid may be used as an adjunct to control inflammation, erythema and itching. If a symptomatic response is not noted within a few days to a week, the local applications of corticosteroid should be discontinued until the infection is brought under control. Occlusive dressing should not be applied if there is an elevation of body temperature. Topical corticosteroids should be used with caution on lesions close to the eye.

DOSAGE: As directed by the physician.
INSTRUCTIONS: Store at 20°C to 25°C excursions permitted to 15°C to 30°C.Protect from sunlightand heat.

PRESENTATION:
DENSID™ Cream 0.05% w/w is available in PVC tube.
DENSID™ Ointment 0.05% w/w is available in PVC tube.

صرف بیرونی استعمال کے لئے

خوراک اور طریقہ استعمال: معالج کی ہدایت کے مطابق استعمال کریں۔
ہدایات: ۲۰ سے ۲۵ ڈگری سینٹی گریڈ پر رکھیں۔ محفوظ کرنے کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے۔
سورج کی روشنی اور گرمی سے محفوظ رکھیں۔

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