For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

ATONIDE CREAM

1. Generic Name

Desonide Cream 0.05% w/w

2. Qualitative and quantitative Composition:

Composition:

Desonide U.S.P…….……..0.05% w/w

Preservatives:

Methyl Hydroxybenzoate I.P……...0.08% w/w

Propyl Hydroxybenzoate I.P…….0.04% w/w

The Excipient used are Almond Oil, Sweet, Beeswax, White, Butylated Hydroxy Toluene, Caprylic/Capric Triglyceride, Cetyl Alcohol, Desonide, Disodium EDTA, Emulsifying Wax, Glycerin, Isopropyl Myristate, Light liquid Paraffin, Methylparaben, Propylene Glycol, Propylparaben, Sorbitan Monostearate, Stearic Acid, Tween 60, Xiameter PMX 200/350

3. Dosage form and strength

Dosage form: Cream

Strength: Desonide (0.05 % w/w)

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for the treatment of relief of the inflammatory and pruritic manifestation of corticosteroid responsive dermatosis.

4.2 Posology and method of administration

Atonide cream, 0.05% should be applied to the affected area as a thin film two to four times daily depending on the severity of the condition. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary. Atonide cream, 0.05% should not be used with occlusive dressings.

4.3 Contraindications

Atonide cream, 0.05% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

4.4 Special warnings and precautions for use

Systemic absorption of topical corticosteroids can produce reversible hypothalamicpituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemicabsorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests. Patients receiving superpotent corticosteroids should not be treated for more than two weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppressions.

One of ten patients treated for one week under occlusion (30% of body surface) with desonide cream, 0.05% developed HPA axis suppression as determined by metapyrone testing.

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 corticosteroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, desonide cream, 0.05% should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of desonide cream, 0.05% should be discontinued until the infection has been adequately controlled.

Desonide cream, 0.05% should not be used in the presence of infection at the treatment site, hypersensitivity to corticosteroids, or pre-existing skin atrophy.

Desonide cream, 0.05% should not be used in the eyes.

4.5 Drugs interactions

No data available

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Teratogenic Effects:

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Animal reproductive studies have not been conducted with desonide cream, 0.05%. It is also not known whether desonide cream, 0.05% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate and well controlled studies in pregnant women. Desonide cream, 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not

known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when desonide cream, 0.05% is administered to a nursing woman..

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

In controlled clinical trials, the total incidence of adverse reactions associated with the use of desonide cream, 0.05% was approximately 1%. These adverse reactions were pruritus, pain, folliculitis, rash, peripheral edema, pustular rash, sweating, erythema, irritation, and burning. Laboratory abnormalities were found in 3% of the patients. These were hyperglycemia (2%) and liver function abnormality (1%). The following additional local adverse reactions have been reported infrequently with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in approximate decreasing order of occurrence: dryness, folliculitis, acneiform eruptions, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, miliaria, burning and hypopigmentation..

Reporting of adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting By reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

Topically applied desonide cream, 0.05% can be absorbed in sufficient amounts to produce systemic effects.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Like other topical corticosteroids, desonide has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However corticosteroids are thought to act by the induction of phospholipase A inhibitory proteins, collectively called lipocortins. It is postulated that these

proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A .

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Studies performed with desonide cream, 0.05% indicate that it is in the low range of potency as compared with other topical corticosteroids.

6 Nonclinical properties

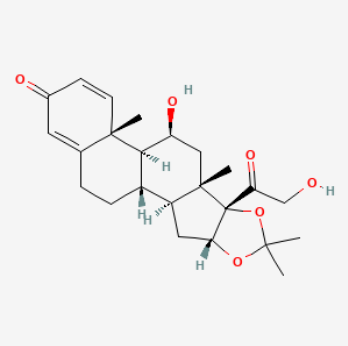
6.1 Animal Toxicology or Pharmacology

Long-term animal studies have not been performed to evaluate the carcinogenic, mutagenic, or fertility impairment potential of desonide cream, 0.05%.

7 Description

Desonide:

Desonide is (1S,2S,4R,8S,9S,11S,12S,13R)-11-hydroxy-8-(2-hydroxyacetyl)-6,6,9,13-tetramethyl-5,7-dioxapentacycl, The empirical formula is $C_{24}H_{32}O_6$ and its molecular weight is 416.5 g/mol. The structural formula is:



Atonide Cream:

Atonide are Opaque white colored cream. The Excipient used are Almond Oil, Sweet, Beeswax, White, Butylated Hydroxy Toluene, Caprylic/Capric Triglyceride, Cetyl Alcohol, Desonide, Disodium EDTA, Emulsifying Wax, Glycerin, Isopropyl Myristate, Light liquid Paraffin, Methylparaben, Propylene Glycol, Propylparaben, Sorbitan Monostearate, Stearic Acid, Tween 60, Xiameter PMX 200/350

8 Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

ATONIDE CREAM is available in pack of 20 gm.

8.4 Storage and handing instructions

Do not store above 30°C. Do not freeze.

Keep the tube tightly closed after use.

Keep out of reach of children.

9 Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products).

10 Details of manufacturer

Stedman Pharmaceutical Pvt. Ltd.,

C-4, SIDCO Pharmaceutical Complex,

Alathur, Thiruporur – 603 110,

Tamilnadu, India.

11 Details of permission or licence number with date

Mfg. Licence. No.: 308 Issued on: 04.12.2017

12. Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

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