TO BE SOLD BY RETAIL ON PRESCRIPTION OF DERMATOLOGIST ONLY

Cortaz Foam

1. **Generic Name**

Clobetasol Propionate Topical Foam 0.05% w/w

2. **Qualitative and quantitative Composition:**

Contains

Clobetasol Propionate IP.....0.05 % w/w

Phenoxyethanol IP (As preservative).....1.0% w/w

In aqueous base ……q.s.

Propellant De-odorised…… q.s.

(Admixture of Propane, Isobutane, Butane)

Excipients used are Hexylene glycol, Ceteareth 20, Phenoxyethanol, Povidone K30, Glycerin, Cetyl alcohol, Polysorbate 60, Citric acid anhydrous, Potassium citrate, and Propellant deodorized.

3. **Dosage form and strength**

Dosage form: Topical Foam

Strength: 0.05% w/w

4. **Clinical particulars**

4.1. Therapeutic indication

Treatment of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older.

4.2. Posology and method of administration

Posology

For external use only

Shake well before every use.

Dosage: As directed by the Dermatologist.

Adults and children above 12 years of age:

Apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. The application frequency should be gradually reduced.

Repeated short courses of Clobetasol may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.

Clobetasol propionate foam, 0.05% contains a topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks for the relief of the inflammatory and pruritic

manifestations of corticosteroid responsive dermatoses and up to 2 additional weeks in localized lesions (less than 10% body surface area) of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment with Clobetasol propionate foam, 0.05%. The total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

In very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of Clobetasol can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

Rarely, occlusion is necessary. In cases where an occlusive dressing is applied, caution is needed in order to avoid the risk of local and systemic adverse events.

Clobetasol should only be used for not more than 5 days on the face and eyelids.

Method of administration

Guidance on how to apply the Topical Foam

Step 1: **Shake the can before every use**. (See Figure 1)

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Figure 1

Step 2: Invert the can and press the nozzle to dispense foam on palm or fingertips (See Figure 2)

Figure 2

Step 3: Gently massage the foam on the affected area until it disappears (see Figure 3)

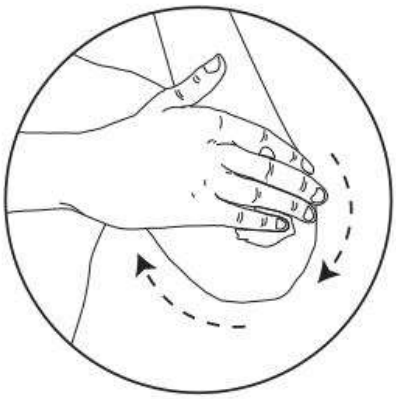
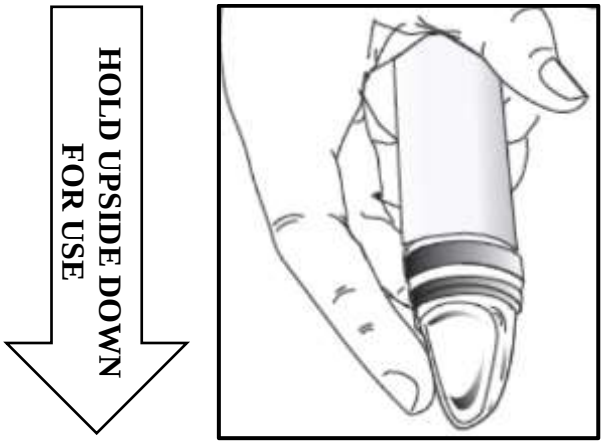


Figure 3

Step 4: Wash your hands after using foam. (See Figures 4)

Figure 4



SHAKE WELL BEFORE EVERY USE

Children below 12 years:

Clobetasol is not recommended in children below 12 years.

4.3. Contraindications

- Rosacea.
- Acne vulgaris
- Perioral dermatitis

- Perianal and genital pruritus
- Primary cutaneous viral infections (e.g. herpes simplex, chickenpox)
- Hypersensitivity to the active substance or to any of the excipients.
- The use of Clobetasol skin preparations is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (E.g. impetigo)
- Dermatoses in children under 12 years of age, including dermatitis and napkin eruptions.

4.4. Special warnings and precautions for use

Contents under pressure. Do not puncture or incinerate container or expose to heat.

Warning: Flammable, avoid proximity to flame or smoking during and immediately after

Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion. If Clobetasol is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.

If used in children or on the face, courses should be limited if possible, to five days and occlusion should not be used.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If Clobetasol does enter the eye, the affected eye should be bathed in copious amounts of water.

Visual disturbance

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.

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

During application of corticosteroids on large areas, especially under (plastic) occlusion or in skin folds, increased absorption may occur, which could lead to adrenal function inhibition.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

4.5. Drugs interactions

No interaction studies have been performed.

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

Pregnancy

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to humans has not been established, therefore, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

Breast-feeding

The safe use of clobetasol propionate during lactation has not been established.

It is not known whether the topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk.

Administration of clobetasol propionate during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation clobetasol propionate should not be applied to the breasts to avoid accidental ingestion by the infant.

Fertility

There are insufficient fertility data available to indicate whether clobetasol propionate has any effect on fertility.

4.7. Effects on ability to drive and use machines

Clobetasol is not expected to have any effects on the ability to drive and use machines.

4.8. Undesirable effects

The following adverse reactions have been identified during post-approval use of clobetasol propionate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The frequency of these adverse events has therefore been classified as “unknown”.

Immune system disorders

Hypersensitivity

- Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment.

- If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders

Features of Cushing's syndrome

- As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas can result in sufficient systemic absorption to produce the features of Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the nappy may act as an occlusive dressing.
- Provided the weekly dosage is less than 50g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

Adrenal insufficiency on abrupt withdrawal

Eye disorders

Vision blurred.

Vascular disorders

Dilatation of the superficial blood vessels

- Prolonged and intensive treatment with highly active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when skin folds are involved.

Skin and subcutaneous tissue disorders

- Local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis.
- Prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes, such as thinning and striae.
- Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

Clobetasol may induce steroid-rosacea and steroid-acne.

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

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

5. Pharmacological properties

5.1. Mechanism of Action

Like other topical corticosteroids, clobetasol propionate 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_2 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_2.

5.2. Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, very potent, dermatological preparations (Group IV), ATC code: D07 AD01 Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

5.3. Pharmacokinetic properties

Topical corticosteroids can be absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the product formulation and the integrity of the epidermal barrier. Occlusion, inflammation, and/or other disease processes in the skin may also increase percutaneous absorption. Once absorbed Page 7 of 14 through the skin, topical corticosteroids are metabolized, primarily in the liver, and are excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

Clinical Data

Efficacy

A multicentre, assessor-blind, randomized, active controlled, parallel design study was conducted by Torrent Pharmaceuticals Limited comparing efficacy and safety of clobetasol propionate topical foam 0.05% vs. clobetasol propionate lotion 0.05% in patients with mild to moderate plaque type psoriasis. A total of 232 patients were randomized to apply foam (n=117) or lotion (n=115). Of these 232 randomized patients, 116 (50.0%) had scalp while remaining 116 (50.0%) had non-scalp psoriasis. Study drugs were self-administered by patients twice daily (morning and evening) at a weekly dose not exceeding 50 g (or 50 mL) for two weeks by scalp and non-scalp psoriasis patients.

At end of treatment (or Week 2), 63.5% of patients who received clobetasol foam had Investigator's Static Global Assessment Score (ISGA) of 0 (clear) or 1 (almost clear) versus 58.2% on Clobetasol Propionate lotion. A higher proportion of patients with scalp psoriasis in the Clobetasol Propionate foam achieved ISGA scores of 0 or 1 at Week 2 than patients in the Clobetasol Propionate lotion arm, 82.8% vs. 70.9%, respectively. However, for non-scalp psoriasis, ISGA scores of 0 or 1 at Week 2 were similar i.e., 43.9% vs. 45.5%, for Clobetasol Propionate foam and Clobetasol Propionate lotion respectively.

A higher proportion of patients with both scalp and non-scalp psoriasis in the Clobetasol Propionate foam achieved Subject's Global Assessment Scores of 0 or 1 at Week 2 than patients in the Clobetasol Propionate lotion (65.2% vs. 53.6%). In addition, no statistically significant difference between foam and lotion based on climatic conditions was observed.

A greater change in the scores of target lesion signs of scalp psoriasis from baseline to week 2 was observed with Clobetasol Propionate foam as compared to Clobetasol Propionate lotion; erythema (-1.5 ± 0.81 vs -1.4 ± 0.85), scaling (-1.7 ± 0.90 vs. -1.5 ± 0.86), plaque thickness (-1.6 ± 0.89 vs. -1.5 ± 0.86) and pruritus (-1.5 ± 1.01 vs -1.5 ± 0.88).

In addition, total vehicle score for all the patients was statistically significantly higher in patients applying foam compared to the ones applying lotion that directs improved patient compliance. In addition, treatment with Clobetasol Propionate foam resulted in statistically significant ($p < 0.05$) vehicle acceptance advantage in ease of applicability, quick spread ability, lesser feel of greasiness/ oiliness on touch and overall vehicle acceptance score as compared with Clobetasol Propionate lotion.

Adverse effects

A total of 9 events in 7 (6.1%) patients applying Clobetasol Propionate foam and 6 events in (5.5%) patients applying Clobetasol Propionate lotion were recorded. Most commonly observed adverse event was pruritus in both scalp and non-scalp psoriasis patients.

In brief, treatment with Clobetasol Propionate foam resulted in significant improvement in scalp and non-scalp psoriasis, was safe, well tolerated and offered a significantly higher patient usage experience and compliance advantage as compared with Clobetasol Propionate lotion.

6. Nonclinical properties

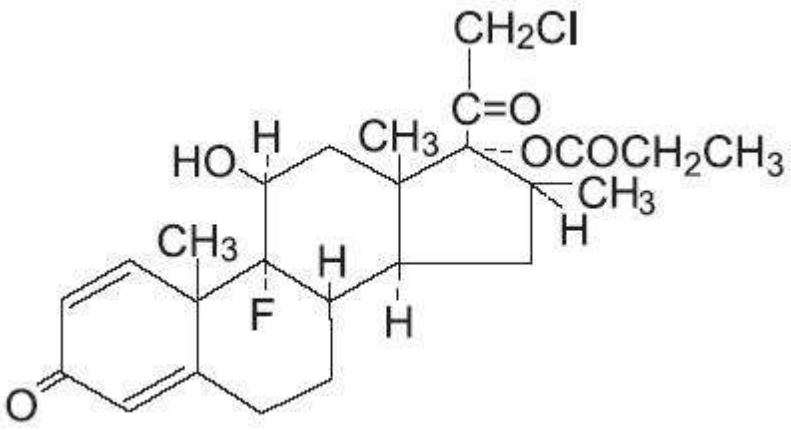
6.1. Animal Toxicology or Pharmacology

Parenteral administration of corticosteroids, including clobetasol propionate, to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine Page 8 of 14 growth retardation. Animal studies have indicated that intrauterine exposure to corticosteroids may contribute to the development of cardiovascular and metabolic diseases in adult life, but there is a lack of evidence for the occurrence of such effects in humans.

7. Description

Cortaz Foam contain the active compound Clobetasol propionate, a synthetic corticosteroid, for topical dermatologic use. A white or almost white, crystalline powder, freely soluble in acetone, sparingly soluble in ethanol (95 percent) and practically Insoluble in water. Clobetasol, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Chemically, clobetasol propionate is 21-chloro-9α-fluoro-11b-hydroxy-16ß-methylpregna-1, 4-diene-3, 20-dion- 17α - yl propionate and it has the following structural formula:



Clobetasol propionate has the molecular formula $C_{25}H_{32}ClFO_5$ and a molecular weight of 467.

Cortaz Foam is white coloured foam containing Clobetasol propionate IP with excipients, Hexylene glycol, Ceteareth 20, Phenoxyethanol, Povidone K30, Glycerin, Cetyl alcohol, Polysorbate 60, Citric acid anhydrous, Potassium citrate, and Propellant deodorized.

8. Pharmaceutical particulars

8.1. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

8.2. Shelf-life

Do not use later than the date of expiry.

8.3. Packaging information

Cortaz Foam is available in 50g Aluminium can.

8.4. Storage and handing instructions

Store below 30°C. Protect from light.

Caution: Do not refrigerate. Do not expose to high temperatures

Keep out of reach of children

Shake well before every use

For external use only

9. Patient Counselling Information

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

- Have any allergies
- Have kidney or liver problems
- 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

Torrent Pharmaceuticals Ltd.

Indrad – 382271, Dist. - Mehsana, INDIA

At: Plot No. B- 16, M.I.D.C., Waluj

Dist. – Aurangabad

11. Details of permission or licence number with date

AD/373-A issued on 13.03.2020

12. Date of revision

FEB 2025

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/CORTAZ FOAM/FEB-2025/03/PI