Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

CACHDERM-N 30gm cream

2. Qualitative and quantitative composition

Each 1gm of Cachderm-N cream contains:
Neomycin Sulfate BP 8.0 mg
Clotrimazole BP 10.0 mg
Beclomethasone Dipropionate BP 0.25 mg

Excipients with known effect:
Cetostearyl Alcohol BP 100.0mg
Propylene Glycol BP 60.0mg
Chlorocresol BP 1.0mg
For a full list of excipients, see section 6.1

3. Pharmaceutical form

Semi-solid dosage form (cream).

White semi-solid mass filled in printed laminated tube.

4. Clinical particulars

4.1 Therapeutic indications

Cachderm-N Cream contains the active compound Beclomethasone Dipropionate (a synthetic corticosteroid), Clotrimazole and Neomycin for topical dermatologic use.

Beclomethasone Dipropionate is an anti-inflammatory, synthetic, halogenated steroid having the chemical name, 9-Chloro-11(beta), 17,21-trihydroxy-16(beta)- methylpregna-1, 4-diene-3, 20-dione 17,21-dipropionate. Clotrimazole: An Imidazole antifungal drug, for topical use in superficial fungal infections is chemically designated as 1-(alpha-2-Chlorotrityl) Imidazole. Neomycin sulphate, an amino glycoside antibiotic, is the sulphate salt of neomycin B and C, produced by the growth of Streptomycin fradiae.

Cachderm-N cream (Beclomethasone Dipropionate/Neomycin/Clotrimazole) is a topical medication used to prevent the growth of fungal cells. It is primarily used for athlete`s foot and jock itch although it can also benefit many other fungal based skin infections.

Cachderm-N Cream is indicated for the relief of the inflammatory manifestations of corticosteroid responsive dermatoses when complicated by secondary infection caused by organisms sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected. Such disorders include: Chronic dermatitis of the extremities, balanoposthitis, eczematoid dermatitis, contact dermatitis, follicular dermatitis, parakeratosis, paronychia, anal pruritus, intertrigo, impetigo, neurodermatitis, angular stomatitis, photosensitivity dermatitis, lichenified inguinal dermatophytosis and tinea infections such as tinea pedis, tinea cruris and tinea corporis. As with other highly

active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

4.2 Posology and method of administration

Route of administration: Cutaneous Creams are especially appropriate for moist or weeping surfaces.

Betamethasone + Clotrimazole + Neomycin is a combination of three medicines: Betamethasone , Clotrimazole and Neomycin. Betamethasone is a steroid which blocks the production of certain chemical messengers (prostaglandins) that make the skin red, swollen and itchy. Clotrimazole is an antifungal which stops the growth of fungi while Neomycin is an antibiotic which stops bacterial growth in the skin. Together, they treat your skin infection effectively.

Use this medication on the skin only. Clean and thoroughly dry the area to be treated. Apply a thin layer of the medication to the affected area and gently rub in, usually twice daily (in the morning and evening) or as directed by your doctor. Wash your hands after using unless you are using this medication to treat the hands. Do not wrap, cover, or bandage the area unless directed to do so by your doctor. Wear loose-fitting clothes after applying the medication to the groin area.

Do not apply the medication in the eyes, nose, mouth, or inside the vagina. If you do get the medication in those areas, flush with plenty of water.

The dosage and length of treatment depends on the type of infection being treated. Ringworm or jock itch is usually treated for 2 weeks, and athlete's foot is usually treated for 4 weeks. Do not use more than 45 grams of the cream or 45 milliliters of the lotion per week unless directed and closely monitored by your doctor. Do not apply more often or use longer than prescribed. This may increase the risk of side effects.

Use this medication regularly to get the most benefit from it. To help you remember, use it at the same times each day. Continue to use this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

Inform your doctor if your condition worsens or does not improve after 1 week of treatment for jock itch or ringworm or 2 weeks of treatment for athlete's foot.

4.3 Contraindications

Cachderm-N is contraindicated in those patients with a history of sensitivity to any of its Components or to other corticosteroids or imidazoles.

If irritation or sensitisation develops with the use of Cachderm-N cream, treatment should be discontinued, and appropriate therapy instituted.

Cachderm-N cream is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections.

Cachderm-N Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components.

Use in Pediatric patients under 12 years of age is not recommended.

4.4 Special warnings and precautions for use

Cachderm-N Cream should not be used with occlusive dressings. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided, particularly in infants and children where adrenal suppression may occur even without occlusion. If irritation or sensitization develops, treatment should be discontinued, and appropriate remedial therapy instituted. In the presence of bacterial or viral infection, an appropriate antibacterial or antiviral agent should be administered concurrently. If response does not occur promptly, Cachderm-N should be discontinued until the infection has been controlled adequately. Systemic absorption of topical corticosteroids will be increased if extensive body surface areas or skin folds are treated. Suitable precautions should be taken under these conditions or when long term use is anticipated, particularly in infants and children.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

Hypothalamic-pituitary adrenal axis suppression. Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children includes linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension includes bulging fontanelles, headaches, and bilateral papilloedema. The safety and effectiveness of Cachderm-N in children below the age of 12 has not been established.

Cachderm-N Cream is not intended for ophthalmic use

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from 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. 3 Manifestations of Cushing syndrome, hyperglycemia, and glycosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy.

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

If irritation or sensitization develops with the use of Cachderm-N Cream, treatment should be discontinued and appropriate therapy instituted. Prolonged use of topical antibiotics occasionally may result in overgrowth of no susceptible organisms. If this occurs or if irritation, sensitization or

super infection develops, treatment with Cachderm-N Cream should be discontinued and appropriate therapy instituted.

4.5 Interaction with other medicinal products and other forms of interaction

Antagonism with polyene antibiotics.

4.6 Pregnancy and Lactation

Pregnancy

Pregnancy & Nursing Mothers:

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class 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 in large amounts or for prolonged periods of time in pregnant patients. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use:

Safety and effectiveness of Cachderm-N Cream in pediatric patients have not been established. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

There was no evidence of carcinogenicity in the study conducted in rats. Studies to assess the mutagenic potential of Beclomethasone Dipropionate have not been conducted. Impairment of fertility, as evidenced by inhibition of the estrous cycle in dogs, was observed following treatment by the oral route at a dose of 0.5 mg/kg/day.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Adverse reactions reported for Cachderm-N include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection. Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin. Reactions to betamethasone dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria, capillary fragility (ecchymoses) and sensitisation. In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension.

Reporting of Adverse Drug Reactions

Healthcare professionals are asked to report any suspected adverse drug reactions via the Pharmacy and Poisons Board's; Pharmacovigilance-Electronic-Reporting-System (PvERS)https://pharmacyboardkenya.org

4.9 Overdose

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress hypothalamic pituitary adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercriticism, including Cushing's disease. Excessive or prolonged use of topical antibiotics may lead to overgrowth of no susceptible organisms in lesions. Appropriate symptomatic treatment is indicated.
Acute hyper corticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised. If overgrowth by non-susceptible organisms occurs, stop treatment with Cachderm-N Cream and institute appropriate therapy

5. Pharmacological properties

5.1 Pharmacodynamic properties

Beclomethasone 17, 21-dipropionate is a diester of Beclomethasone which has potent glucocorticosteroid and weak mineral corticosteroid activity. The mechanism for the anti-inflammatory action of Beclomethasone Dipropionate is unknown. It is postulated that topical steroids control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Corticosteroids are also thought to act by the induction of phospholipids A2 inhibitory protein.

Clotrimazole exerts antifungal effects by inhibition of fungal sterol synthesis. It appears to inhibit the enzymatic conversion of 2,4-methylenedihydrolanosterol to demethylsterol, the precursor to ergo sterol, which is an essential building block of the cytoplasmic membrane of the fungi. Clotrimazole is a broadspectrum antifungal agent that inhibits the growth of most fungi pathogenic to man, including the Candida and Dermatophytes (Trichophyton, Microsporum, Epidermophyton).

Neomycin acts on bacteria by interfering with bacterial protein synthesis by binding to 30s ribosomes. The antibacterial spectrum of Neomycin includes specific organisms which are susceptible to it and generally includes all medically important aerobic gram-negative bacilli except Pseudomonas Aeruginosa. Anaerobic bacteria are resistant. Staphylococcus aureus and Staph. Epidermidis are highly sensitive, but all streptococci are relatively resistant.

5.2 Pharmacokinetic properties

Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneously absorption of topical corticosteroids is determined by many factors, 2 including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may Increase percutaneously absorption. Systemic absorption following use of topical Clotrimazole preparations is very low. Estimated bioavailability is less than 0.5%. Clotrimazole concentrations achieved in the epidermal layers exceed the minimal inhibitory concentrations (MICs) for almost all pathogenic fungi.

1.Betamethasone Dipropionate: Topical Absorption: It is absorbed into the systemic circulation and the amount is depending on the potency, amount applied and the nature of the skin at the site of application. Absorption increases at the site of skin damage, inflammation or occlusion.

2. Neomycin: Neomycin is poorly absorbed from the gastrointestinal tract and after topical administration an insufficient amount is absorbed to produce systemic effects. Absorption has been reported to occur from wounds and inflamed skin. After absorption neomycin is rapidly excreted by the kidneys in active form.

3. Clotrimazole: Absorption is minimal after topical administration.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the product.

6. Pharmaceutical Particulars

6.1 List of Excipients

Quantity (mg/gm):

1. Beclomethasone Dipropionate USP 0.25mg
2. Clotrimazole BP 10.0mg
3. Neomycin Sulphate BP 8.0mg
4. Cetomacrogol Emulsifying Wax BP 25.0mg
5. Cetostearyl Alcohol BP 100.0mg
6. Propylene Glycol BP 60.0mg
7. Light Liquid Paraffin BP 50.0mg
8. Disodium EDTA BP 1.0mg
9. Chlorocresol BP 1.0mg
10. Sodium Metabisulphite BP 1.0mg
11. Purified Water BP q.s.

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

24 Months

6.4 Special Precautions for storage

Store at a temperature not exceeding 30°C. Do not freeze. Keep out of reach of children.

6.5 Nature and Content of container

30 g semi-solid mass filled in printed lami tube & enclosed in carton along with pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

Cachet Pharmaceuticals Private Limited
Address: 415, Shah Nahar Ind. Estate,
Dr. E. Moses Road, Worli, Mumbai-400 018
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8. Marketing Authorization Number

CTD10463

9. Date of first authorization/renewal of the authorization

09/02/2024

10. Date of revision of the text

17/01/2025