Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
CACHDERM-G 30gm cream

2. Qualitative and quantitative composition
Each 30gm of Cachderm-G cream contains:
Gentamicin Sulfate USP Eq. Gentamicin base 0.003g
Clotrimazole BP 0.3 g
Beclomethasone Dipropionate BP 0.0075 mg

Excipients with known effect:
Cetosteryl alcohol 1.5g
Chlorocresol BP 0.036g
Propylene glycol 2.4g
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
Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream is indicated for the relief from Impetigo, Furunculosis, secondary infected dermatoses, Intertringinous eruptions, Atopic and discoid eczema, dermatitis, psoriasis, lichen simplex, discoid lupus erythematosus. Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream is commonly used for the treatment and prevention of the symptoms of discomfort of many types of skin problems.

Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream is also used for the treatment of a variety of skin conditions such as contact dermatitis, atopic dermatitis, eczema, lichen planus, bug bites, burns, psoriasis, chronic discoid lupus erythematosus, alopecia aerate, mycosis fungoides, dermatophytes and fungus or yeast infections.

Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream reduce or inhibit the actions of chemicals in the body that cause inflammation, redness, and swelling. Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream works by reducing irritation and itching on the affected areas of the skin. When Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream applied to the skin it is absorbed into the skin cells. Here Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream work by preventing the release of certain chemicals from the cells. These chemicals are important in the immune system, and are released as a result of allergy or irritation. They cause blood vessels to widen, resulting in the affected area of skin becoming red, swollen, itchy and

painful, such as is seen in dermatitis or eczema. By decreasing the release of these chemicals in the skin, Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream reduces inflammation and relieves itch.

4.2 Posology and method of administration

Adults and children over the age of 12 years.
Paediatric population
Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream is not recommended for children under the age of twelve years.

Method of administration
Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidacies) or for four weeks (tinea pedis).

4.3 Contraindications

Hypersensitivity to any of the ingredients.
If irritation or sensitization develops with the use of Cachderm-G cream, treatment should be discontinued and appropriate therapy instituted.
Rosacea, acne, peri-oral dermatitis, tuberculosis of the skin and varicose ulcers.
Skin lesions caused by infections with viruses (e.g. herpes simplex, vaccine or varicella), fungi (e.g. candida, tinea) or bacteria (e.g. impetigo).

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream **should not be used during pregnancy**. The use of Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream is not recommended during breast feeding.

4.4 Special warnings and precautions for use

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

CACHDERM-G CREAM SHOULD NOT BE USED WITH OCCLUSIVE DRESSING.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalized pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

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.

Cachderm-G Cream is not intended for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

Paediatric population

• Long term continuous therapy should be avoided in all children irrespective of age.

• Cachderm-G cream should not be used with adhesive dressing.

• The safety and effectiveness of Cachderm-G cream has not been established in children below the age of 12.

• If used on children, courses should be limited to 5 days.

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 include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

Cachderm-G cream contains:

Cetostearyl alcohol which may cause localised skin reactions (e.g. contact dermatitis).

Propylene glycol which may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns)

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Pregnancy and Lactation

Pregnancy

Certain medicines should not be used during pregnancy or breastfeeding. However, other medicines may be safely used in pregnancy or breastfeeding providing the benefits to the mother outweigh the risks to the unborn baby. Always inform your doctor if you are pregnant or planning a pregnancy, before using any medicine.

This medicine should not be used during pregnancy unless considered essential by your doctor. If it is prescribed by your doctor it should not

be used on large areas of skin, underneath airtight dressings, or for prolonged periods of time. Consult your doctor for further information.

Lactation
This medicine should not be used during breastfeeding unless considered essential by your doctor. If it is prescribed by your doctor it should not be used on large areas of skin, underneath airtight dressings or for prolonged periods of time. If it is applied to the breasts it should be washed off carefully before breastfeeding and then reapplied afterwards.

4.7 Effects on ability to drive and use machines

Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions reported for Cachderm-G cream include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection. Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritis, urticaria and general irritation of the skin.
Reactions to betamethasone Dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation perioral dermatitis, and 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 have been reported.

Delayed type hypersensitivity reactions have been reported during use of Gentamicin; sensitization has been reported following prolonged use. Ototoxicity and nephrotoxicity have been reported when applied to large surfaces or damaged skin.

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

Acute overdosage with topical application of Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate Cream is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.
Toxic effects are unlikely to occur following accidental ingestion of Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulphate

Cream. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: D07AC01, D01AC20 & D06AX04

Pharmacotherapeutic group: Antifungal, Antibacterial, Anti inflammatory

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).

Gentamicin binds to 30s and 50s ribosomal subunits of susceptible bacteria disrupting protein synthesis, thus rendering the bacterial cell membrane defective.

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 in to 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. Gentamicin Sulfate: Gentamicin can be absorbed through inflamed skin. Once absorbed, it is rapidly excreted unchanged through the kidneys. The half-life is approximately 2 to 3 hours.

3. Clotrimazole: Absorption is minimal after topical administration.

5.3 Preclinical safety data

Pre-clinical effects were seen only at exposures which are extremely unlikely to cause concern for humans under normal conditions of use. Mutagenicity studies revealed no risks to man.

6. Pharmaceutical Particulars

6.1 List of Excipients

Batch Size 30 gm:

1. Beclomethasone Dipropionate USP 0.0075g
2. Clotrimazole BP 0.3g
3. Gentamicin Sulphate BP 0.03g
4. Macrogol Cetostearyl Ether BP 0.375g
5. Cetostearyl Alcohol BP 1.5g
6. Propylene Glycol BP 2.4g
7. Light Liquid Paraffin BP 2.1g
8. Disodium Edetate BP 0.03g
9. Chlorocresol BP 0.036g
10. Dimethicone BP 1.2g
11. Glyceryl Monostearate BP 0.6g
12. Petroleum jelly BP 0.9g
13. Purified water BP qs

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
Maharashtra, India
Telephone: +91-22-24970011 / +91-22-40829999

8. Marketing Authorization Number

CTD10462

9. Date of first authorization/renewal of the authorization
09/02/2024

10. Date of revision of the text
17/01/2025