

Beclomethasone Dipropionate & Gentamicin

CLOMIGEN[®]

COMPOSITION:

Beclomethasone Dipropionate 0.025% w/w

Gentamicin 0.1% w/w

PHARMACOLOGICAL CLASSIFICATION:

Topical steroid with Antimicrobial agent.

PHARMACOLOGICAL ACTION:

Beclomethasone Dipropionate is a potent glucocorticoid which has anti-inflammatory, antipruritic and vasoconstrictive properties. Corticosteroids are hormones that produced naturally by the adrenal glands, and have many important functions, including control of inflammatory responses. Clomigen Cream is a synthetic corticosteroid and used to decrease inflammation in the skin. As a cream, it is used to treat severe inflammatory skin disorders (eg. eczema) unresponsive to less potent steroids, but is generally avoided in the treatment of psoriasis due to the risk of rebound on withdrawal. Clomigen Cream is also used to treat the inflammation caused by a number of conditions such as allergic reactions, eczema, and psoriasis.

INDICATIONS:

Clomigen CREAM is indicated for the relief from Impetigo, Furunculosis, secondary infected dermatoses, Napkin rashes, Otitis externa, Intertriginous eruptions, Atopic and discoid eczema, dermatitis, psoriasis, lichen simplex, discoid lupus erythematosus.

Clomigen Cream is commonly used for the treatment and prevention of the symptoms of discomfort of many types of skin problems.

Clomigen 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, severe diaper rash, chronic discoid lupus erythematosus, alopecia areata, mycosis fungoides, dermatophyte and fungus or yeast infections.

Clomigen Cream reduces or inhibits the actions of chemicals in the body that cause inflammation, redness, and swelling. Clomigen Cream works by reducing irritation and itching on the affected areas of the skin.

When Clomigen Cream applied to the skin it is absorbed into the skin cells. Here Clomigen Cream works 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, Clomigen Cream reduces inflammation and relieves itch.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients.

Rosacea, acne, peri-oral dermatitis, tuberculosis of the skin and varicose ulcers. Skin lesions caused by infections with viruses (e.g. herpes simplex, vaccinia 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 **CLOMIGEN CREAM** should not be used during pregnancy.

The use of **CLOMIGEN CREAM** is not recommended during breast feeding.

WARNINGS:

For external use only. Do not use in or around the eye.

DOSAGE AND DIRECTIONS FOR USE:

Topical, to the skin as a cream once or twice a day.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

CLOMIGEN CREAM should be used for short courses only, as prolonged and intensive treatment may cause local atrophic changes in the skin such as stria, thinning, loss of elasticity, dilatation of the superficial blood vessels, telangiectasia and ecchymosis.

These changes are particularly likely to occur on the face, where occlusive dressings are used or where skin folds are involved. Prolonged use, use of large amounts, treatment of extensive areas, or application to damaged skin, when **CLOMIGEN CREAM** is used and when the occlusive dressing technique is applied can result in sufficient systemic absorption to produce the features of hypercortisonism such as depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland. These effects are most likely to be severe in infants and children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been reported less frequently. In infants the napkin may act as an occlusive dressing, and hence these preparations should not be used in the nappy area for flexural eruptions. Ideally they should not be used in infants and young children at all.

Regular review should be made of the necessity for continuing therapy.

Treatment of psoriasis with **CLOMIGEN CREAM** or its withdrawal) may provoke the pustular form of the disease. If signs of hypersensitivity appear, application should stop immediately. The least potent corticosteroids should be used with particular caution in facial dermatoses, and only for short periods. A steroid rosacea-like facies may be produced. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus, and severe eczema with **CLOMIGEN CREAM**. Topical corticosteroid preparations should be used with caution near the eyes; application to the eyelids may cause glaucoma.

Corticosteroids should never be used in the presence of infection except in conjunction with effective chemotherapy. 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 the skin should be cleansed before a fresh dressing is applied.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excessive or prolonged use of **CLOMIGEN CREAM** may result in systemic absorption of steroid and complications of steroid therapy, especially growth retardation in children, suppression of pituitary adrenal function, increased susceptibility to infection, hyperglycaemia, Cushingoid state and benign intracranial hypertension. Cessation of treatment with appropriate symptomatic and supportive treatment is indicated.

STORAGE:

Keep this medication in the container it came in, tightly closed, and out of reach of children. Keep out of reach of children. Store it in cool & dark place. **DO NOT FREEZE.**

Warning!

- This medicine is for external use on the skin only.
- This medicine should be applied thinly and evenly to the affected area(s) as directed by your doctor.
- Wash your hands thoroughly after applying this medicine, unless the hands are the area being treated.
- Avoid contact of this medicine with open wounds and with the eyes and the moist membranes lining the inside of certain parts of the body, eg mouth, nasal passages (mucous membranes). Rinse with cold water if accidental contact occurs.
- If your doctor has advised you to use dressings with this medicine, the skin should be cleansed before reapplying the cream under a fresh dressing.
- If corticosteroids are used long term, on large areas of skin, raw skin, skin folds, or under airtight dressings (including nappies) they are absorbed into the body more. This increases the risk of local side effects such as skin thinning, and those on other parts of the body, such as a decrease in the production of natural hormones by the adrenal glands. For this reason, continuous, long-term use of this medicine should be avoided wherever possible, particularly in children and on large areas of skin. You should only use airtight dressings over the affected area if instructed by your doctor.
- This medicine should not be used for longer than five days on the face or in children.
- Consult your doctor if your symptoms don't improve, or get worse in the first seven days of treatment. Do not use this medicine for longer than five days without consulting your doctor.
- This preparation may stain skin, hair and fabric. You can protect clothes by covering the treated area with a non-airtight cotton bandage or piece of clean cloth.
- If you think the area of skin you are treating has become infected you should stop using this medicine and consult your doctor.

Contraindicated in

Use on acne (including rosacea), peri-oral dermatitis, scabies, leg ulcers, tuberculous, ringworm or viral skin disease. Untreated fungal or bacterial infections. Extensive or prolonged use in pregnancy. continuous prophylactic use.

If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

Pregnancy and breastfeeding

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.
- 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.

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Presentation

15 gm Tube

For further information, please contact:

Market Planning Department

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