

PRODUCT NAME

CLEAR GEE CREAM

(Betamethasone Dipropionate Cream USP)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

GENERIC NAME: - Betamethasone Dipropionate Cream USP

BRAND NAME - CLEAR GEE

2. Qualitative and quantitative composition

Composition

Betamethasone Dipropionate	USP
Eq. To betamethasone	0.05% w/w
Cream Base	Qs

3. Pharmaceutical form

Cream

A smooth white cream.

4. Clinical particulars

4.1 Therapeutic indications

This medication is used to treat a variety of skin conditions (such as eczema, dermatitis, allergies, rash). Betamethasone reduces the swelling, itching, and redness that can occur in these types of conditions. This medication is a strong corticosteroid.

4.2 Posology and method of administration

Posology

There is no separate dosage schedule for the young or elderly.

Method of administration

Apply a thin film of Betamethasone Dipropionate Cream % to the affected skin areas once daily. In some cases, twice-daily dosage may be necessary. Betamethasone Dipropionate Cream % should not be used with occlusive dressings.

4.3 Contraindications

Contraindicated in patients who are hypersensitive to betamethasone dipropionate, to other corticosteroids, or to any ingredient in this preparation.

4.4 Special warnings and precautions for use

Do not let betamethasone topical get into your eyes or mouth and do not swallow it. Avoid use in the genital and rectal areas and in skin creases and armpits unless directed by your doctor. If you are using betamethasone on a child's diaper area, do not use tight-fitting diapers or plastic pants.

4.5 Interaction with other medicinal products and other forms of interaction

There are 562 drugs known to interact with betamethasone, along with 22 disease interactions, and 2 alcohol/food interactions. Of the total drug interactions, 71 are major, 454 are moderate, and 37 are minor.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Betamethasone is not usually recommended for use when pregnant. A dermatologist (skin care specialist) may prescribe it if they feel the benefits outweigh the risks. Small amounts of betamethasone used on small areas of skin are unlikely to cause any problems in pregnancy.

Lactation:

Only the lower potency corticosteroids should be used on the nipple or areola where the infant could directly ingest the drugs from the skin; topical betamethasone should be avoided on the nipple.

Fertility:

Betamethasone is not usually recommended for use when pregnant. A dermatologist (skin care specialist) may prescribe it if they feel the benefits outweigh the risks. Small amounts of betamethasone used on small areas of skin are unlikely to cause any problems in pregnancy.

4.7 Effects on ability to drive and use machines

Betamethasone Dipropionate Cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Your doctor may want your eyes be checked by an ophthalmologist (eye doctor). Check with your doctor right away if you have a skin rash, blistering, burning, crusting, dryness, flaking of the skin, itching, scaling, severe redness, stinging, swelling, or irritation on the skin.

Reporting of suspected adverse reactions

Betamethasone dipropionate cream include burning, tingling, rash, swelling, and infections. These are not all the possible side effects of clotrimazole and betamethasone dipropionate cream. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

4.9 Overdose

Burning, itching, irritation, or dryness at the application site may occur when this medication is first applied to the skin. This should disappear in a few days as your body adjusts to the medication. If any of these effects last or get worse, notify your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: stretch marks, skin thinning/discoloration, acne, extreme/unwanted hair growth, small red bumps on the skin (folliculitis). Skin infections can become worse when this medication is used. Tell your doctor if redness, swelling, or irritation does not improve. Rarely, it is possible this medication will be absorbed from the skin into the bloodstream. This can lead to side effects of too much corticosteroid. These side effects are more likely in children, and in people who use this medication for a long time or over large areas of the skin. Tell your doctor right away if any of the following side effects occur: unusual/extreme tiredness, weight loss, headache, swelling ankles/feet, increased thirst/urination, vision problems.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action

Glucocorticoids inhibit neutrophil apoptosis and demargination, and inhibit NF-Kappa B and other inflammatory transcription factors. They also inhibit phospholipase A2, leading to decreased formation of arachidonic acid derivatives. In addition, glucocorticoids promote anti-inflammatory genes like interleukin-Corticosteroids like betamethasone can act through nongenomic and genomic pathways.³ The genomic pathway is slower and occurs when glucocorticoids activate glucocorticoid receptors and initiate downstream effects that promote transcription of anti-inflammatory genes including phosphoenolpyruvate carboxykinase (PEPCK), IL-1-receptor antagonist, and tyrosine amino transferase (TAT). On the other hand, the nongenomic pathway is able to elicit a quicker response by modulating T-cell, platelet and monocyte activity through the use of existing membrane-bound receptors and second messengers.

Pharmacodynamic Effects

Corticosteroids bind to the glucocorticoid receptor inhibiting pro-inflammatory signals, while promoting anti-inflammatory signals.¹ Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces.¹

5.2 Pharmacokinetic properties

Patients who require long-term treatment with a corticosteroid should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Betamethasone Dipropionate Cream was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats Betamethasone Dipropionate and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical particulars

6.1 List of excipients

Cetostearyl Alcohol, CM 1000, Propyl Glycol Plain, LLP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dark place .

6.5 Nature and contents of container

Lami tube with cap.

Pack sizes: 30GM

6.6 Special precautions for disposal and other handling

No special requirements

7.0 EXPORTER

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8.0 MANUFACTURER

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9.0 MARKETING AUTHORITY

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