

TRISHIELD
(Beclomethasone, Clotrimazole & Gentamicin Cream)



SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

TRISHIELD

(Betamethasone, Clotrimazole and Gentamicin Cream)

1.2 Strength

Betamethasone Dipropionate USP

Eq. to Betamethasone.....0.05% w/w

Clotrimazole BP.....1.0% w/w

Gentamicin Sulfate BP

Eq. to Gentamicin Base.....0.1% w/w

Chlorocresol BP.....0.1% w/w

(As preservative)

1.3 Pharmaceutical Form

Cream (Topical Dosage form)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone Dipropionate USP

Eq. to Betamethasone.....0.05% w/w

Clotrimazole BP.....1.0% w/w

Gentamicin Sulfate BP

Eq. to Gentamicin Base.....0.1% w/w

Chlorocresol BP.....0.1% w/w

(As preservative)

3. PHARMACEUTICAL FORM

Cream

White colour semisolid ointment.

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4. CLINICAL PARTICULARS

4.1. Therapeutic indications

TRISHIELD is indicated for the treatment of Corticosteroid-responsive dermatoses when complicated by infections caused by bacteria (sensitive to gentamicin) and fungi (sensitive to clotrimazole) or when the possibility of such infections is suspected. The cream is suitable for the use of oozing eczema.

4.2. Posology and method of administration

Posology

A thin film of TRISHIELD Cream should be applied to cover completely the affected and surrounding skin areas twice daily, in the morning and at night. For treatment to be effective, TRISHIELD Cream should be applied regularly.

Duration of Treatment

Duration of therapy varies depending upon the extent and location of disease and patient response. However, if clinical improvement is not achieved by three to four weeks, diagnosis should be reviewed.

Method of administration

FOR DERMATOLOGIC USE ONLY.

4.3. Contra-indications

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

4.4. Special warnings and special precautions for use

If irritation or sensitization develops with use of TRISHIELD Cream or Ointment, treatment should be discontinued and appropriate therapy instituted. Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

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Cross-allergenicity among aminoglycosides has been demonstrated. Systemic absorption of topical corticosteroids or gentamicin will be increased if extensive body surface areas are treated or if occlusive dressings are used, especially over prolonged time periods or in the presence of dermal disruption. Application of gentamicin to open wounds or damaged skin should be avoided. In cases, the undesirable effects which occur following systemic use of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children.

Prolonged use of topical antibiotics occasionally may result in overgrowth of nonsusceptible microorganisms. If this occurs or if irritation, sensitization or superinfection develops, treatment with TRISHIELD Cream should be discontinued and appropriate therapy instituted. TRISHIELD Cream is not for ophthalmic use.

Paediatric Use: Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroids effects than mature patients because of greater absorption due to large skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

4.5. Interactions with other Drug products and other forms of interaction

Not applicable.

4.6. Fertility, Pregnancy and lactation

Since safety of topical corticosteroids use in pregnant women, has not been established, drugs of this class should be used during pregnancy only if the potential benefits 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.

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4.7. Effects on ability to drive and use machines

NA

4.8. Undesirable effects

Adverse reactions to TRISHIELD Cream therapy have been reported very rarely and include skin discoloration, hypochromia, burning, erythema, exudation and pruritus of almost 1000 patients who received clotrimazole therapy topically for indicated dermatomycoses, 95% showed excellent local tolerance. Reported adverse reactions include stinging, blistering, peeling, edema, urticaria and general irritation of the skin. Treatment with gentamicin has produced transient irritation that usually did not require discontinuance of treatment.

The following local adverse reactions have been reported with the use of topical corticosteroids especially under occlusive dressings; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

4.9 Overdose

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease. Since application of ¹⁴C labeled clotrimazole+ to intact or diseased skin under occlusive dressing for six hours did not yield measurable quantities (lower detection limit 0.001 mcg/ml) of radioactive material in the sera of human subjects, overdosage by topical clotrimazole administration is highly improbable.

A single overdose of gentamicin would not be expected to produce symptoms. Excessive or prolonged use of topical gentamicin may lead to overgrowth of lesions by non-susceptible microorganisms.

Treatment: Appropriate symptomatic treatment is indicated. Acute hyper corticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, show withdrawal of corticosteroids is advised. If overgrowth by non-susceptible microorganisms occurs, stop treatment with TRISHIELD Cream and institute appropriate therapy.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Topical corticosteroid and anti-infectives in combination

Mechanism of action

TRISHIELD Cream combines the sustained anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone dipropionate with the broad-spectrum antifungal activity of clotrimazole and the wide-spectrum bactericidal antibiotic activity of gentamicin sulfate. Clotrimazole appears to act on the fungal cell membrane, causing leakage of cell contents. Gentamicin provides highly effective topical treatment in primary and secondary bacterial infections of the skin.

5.2 Pharmacokinetic Properties

Gentamicin Sulfate:

Absorption: NA

Volume of Distribution: NA

Protein Binding: Studies have determined that plasma protein binding of gentamicin is between 0-30% depending on the method of testing

Metabolism: Gentamicin undergoes little to no metabolism.

Route of elimination: Gentamicin is excreted primarily by the kidneys. In patients with normal renal function, 70% or more of an initial gentamicin dose can be recovered in the urine within 24 hours. Excretion of gentamicin is significantly reduced in patients with renal impairment.

Clotrimazole:

Absorption: clotrimazole is generally not significantly absorbed, drug interactions are not a major issue with its use.

Volume of Distribution: The topical form is minimally absorbed in the serum and tissues.

Clotrimazole is a lipophilic drug, and has been shown to be secreted in breastmilk in animal studies. There are limited data available regarding the volume of distribution following oral troche administration.

It should be noted that the use of occlusive dressings with topical steroids significantly increases the absorption, increasing the risk for adverse effects

Protein Binding: 98%

Metabolism: Hepatic (metabolized to inactive metabolites).

Route of elimination: Mainly hepatic.

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Betamethasone Dipropionate:

Absorption: The absorption and potency of any topical corticosteroid including betamethasone depends on the vehicle in which the steroid is delivered. For example, betamethasone dipropionate 0.05% ointment is classified as a highly potent topical steroid, while betamethasone dipropionate 0.05% cream or lotion is considered to be moderately potent.

There are several structural modifications that can determine the potency of a topical corticosteroid. For example, corticosteroids containing a halogen at specific carbons, or that contain esters are more potent due to enhanced lipophilicity. As such, there is a marked difference between topical products containing betamethasone dipropionate vs. betamethasone valerate. Betamethasone dipropionate contains 2 esters which enhances its potency, while betamethasone valerate has only one ester and is less potent.

It should be noted that the use of occlusive dressings with topical steroids significantly increases the absorption, increasing the risk for adverse effects.

Volume of Distribution: In a study that included Indian women of reproductive age, the volume of distribution following a single intramuscular dose of betamethasone phosphate was $94,584 \pm 23,539$ mL(s).

Protein Binding: Betamethasone valerate binds to serum albumin and corticosteroid-binding globulin.

Metabolism: The metabolism of betamethasone yields 6 metabolites. The metabolic processes include 6β hydroxylation, 11β -hydroxyl oxidation, and reduction of the C-20 carbonyl group followed by removal of the side chain.

Route of elimination: Corticosteroids are eliminated predominantly in the urine.

5.3. Preclinical safety data

Not applicable

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6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Chlorocresol, White soft paraffin, C. Wax, Methyl Paraben, Propyl Paraben, E. Wax, Light liquid Paraffin, Propylene Glycol, Na₂HPO₄, NAHPO₄ and DM water.

6.2. Incompatibilities

None

6.3. Shelf life

36 Months.

6.4 Special precautions for storage

Store below above 30 °C.

Protect from light.

Do not freeze. Replace the cap tightly after use.

Keep out of reach of children.

6.5. Nature and contents of container

30 g Lami tube

1X 30 gm tube are packed in one carton pack along with packing leaflet.

6.6. Special precautions for disposal and other handling

There are no special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7.0 Registrant

TRIDENT LIFELINE PVT LTD

Address: 2004, II floor, North Extension Falsawadi, Ring Road

Surat 395003, GUJARAT, India

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(Beclomethasone, Clotrimazole & Gentamicin Cream)



SUMMARY OF PRODUCT CHARACTERISTICS

8.0 Manufacturer

MARS REMEDIES PVT LTD

Address: 635, GIDC Estate, Waghodia-391760, Vadodara, GUJARAT INDIA

9.0 Date of Publication or Revision

Last revised on 23-May-2020

10. DOSIMETRY (IF APPLICABLE)

Not Applicable

11. Instructions for Preparation of Radiopharmaceuticals (If Applicable):

Not Applicable