

Summary of Product Characteristics (SPC)

1. NAME OF THE MEDICINAL PRODUCT

CLOZOLE TRIO (Clotrimazole, Betamethasone and Neomycin Sulfate Cream)

1.1 (INVENTED) NAME OF THE MEDICINAL PRODUCT

Clozole Trio (Clotrimazole, Betamethasone and Neomycin Sulfate Cream)

1.2 STRENGTH

Each gram contains:

- Clotrimazole USP.....1.0 % W/W
- Betamethasone Dipropionate USP equivalent to Betamethasone.....0.05 % W/W
- Neomycin Sulfate BP.....0.5 % W/W
- Cream Base QS
- Chlorocresol (As Preservative) BP.....0.1 % W/W

1.3 PHARMACEUTICAL FORM

Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Quantity per dosage unit in % w/w
Clotrimazole USP	1.000
Betamethasone Dipropionate USP	0.0643
Neomycin Sulphate BP	0.500
Cetomacrogol 1000 BP	3.000
Cetostearyl Alcohol BP	8.000
Methyl Hydroxy Benzoate BP	0.150
Propyl Hydroxy Benzoate BP	0.050
White Soft Paraffin (White Petroleum Jelly) BP	10.000
Parachloro Meta Cresol (Chlorocresol) BP	0.100
Propylene Glycol BP	5.000
Sodium Dihydrogen Phosphate Dihydrate BP	0.025
Carrot Fragrance 290809 IH	0.60
Purified water	100.000

Note:

- BP = British Pharmacopoeia
- USP = United States Pharmacopoeia
- IH = In House Specifications

3. PHARMACEUTICAL FORM

Cream

White, semisolid, smooth cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clozole Trio is indicated for the topical treatment of wide range of eczemas and other inflammatory and allergic infections caused by various bacteria and fungi that are sensible to clotrimazole and neomycin.

These conditions include contact dermatitis, follicular dermatitis, impetigo, intertrigo, eczematoid dermatitis and non-specific pruritus.

4.2 Posology and method of administration

After cleaning the affected area sufficient quantity of Clozole Trio should be applied to affected area to form a thin and even layer, two or three times daily. This treatment should be continued for several days after the disappearance of symptoms. Consult a physician if no improvements

Do not use with occlusive dressings unless directed by a physician.

Not for ophthalmic or intravaginal use.

Method of administration: For external use only.

4.3 Contraindications

Hypersensitivity to Clotrimazole, Neomycin sulphate and Betamethasone dipropionate.

It should not be used in tuberculosis of the skin, varicella, herpes simplex and viral infections of the skin and measles. It should not be applied in open wounds nor in the eyes.

4.4 Special warnings and precautions for use

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Occlusion must not be used.

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

General: Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

If irritation develops, treatment should be discontinued and appropriate therapy instituted.

Pediatric patients may be more susceptible to systemic toxicity.

Use of Clozole trio in the treatment of diaper dermatitis is not recommended.

4.5 Interaction with other medicinal products and other forms of interaction

This medicine is not known to affect other medicines. However, as with all medicines, it is important to tell your doctor or pharmacist what medicines you are already using, including those bought without a prescription and herbal medicines, before you start treatment with this medicine. Similarly, check with your doctor or pharmacist before using any new medicines while using this one, to make sure that the combination is safe.

If you are using other topical medicines or moisturisers on the same area of skin it is recommended that you leave several minutes between applying each product. This is to allow each product time to be absorbed and avoid them mixing on the skin.

If you apply moisturisers shortly before or after applying this medicine these can dilute the corticosteroid and potentially make it less effective. Try to apply your moisturisers at a different time of day, or at least 30 minutes before or after this one.

4.6 Pregnancy and lactation

Pregnancy and Lactation: Teratogenic effects

Pregnancy Category C

There are no adequate and well-controlled studies with Clotrimazole, Betamethasone Dipropionate and Neomycin sulfate in pregnant women. Therefore Clozole trio should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

When applicable this formulation should not be used in large amounts or for prolonged periods during pregnancy.

Nursing Mothers

Because many drugs are excreted in human milk, caution should be exercised when Clozole trio is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Occasionally, hypersensitivity reactions may occur, irritation, acne, telangiectasia, hypertrichosis, skin atrophy and striae. The following local adverse reactions have been reported with topical corticosteroids: itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, skin atrophy, striae, miliaria, capillary fragility (ecchymoses), telangiectasia, and sensitization.

Adverse reactions reported with the use of clotrimazole are: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin.

4.9 Symptoms of Overdosage & Treatment

Acute overdosage with topical application of Clozole trio 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 Clozole trio. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Category: ATC code: D07CC01

Clozole Trio is a combination of a synthetic antifungal agent Clotrimazole; a broad spectrum antibacterial antibiotic Neomycin sulphate; and a potent topical corticosteroid Betamethasone dipropionate.

Pharmacodynamic effects: Clozole trio provides a comprehensive treatment for various inflammatory dermatological disorders superadded with bacterial or superficial fungal infections of the skin. Betamethasone dipropionate is one of the most potent topical corticosteroid available and rapidly controls the symptoms such as itching, redness and scaling.

Many times the inflammatory skin disorders which respond to topical corticosteroids are superadded with bacterial and/or fungal infections of the skin. In these conditions, treatment with anti-inflammatory agents alone is not sufficient and a proper antibiotic has to be added in the regimen.

Clotrimazole is a broad spectrum synthetic antifungal agent which has fungicidal action against all the fungi responsible for superficial fungal infections of the skin. Neomycin sulphate is a broad spectrum antibacterial. Hence, Clozole trio effectively controls inflammatory disorders superadded with bacterial and/or fungal infections of the skin.

5.2 Pharmacokinetic properties

Clozole trio is intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.

Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Inflammation and/or other disease processes in the skin may increase percutaneous absorption of topical corticosteroids. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

5.3 Preclinical safety data

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol 1000 BP
Cetostearyl Alcohol BP
Methyl Hydroxy Benzoate BP
Propyl Hydroxy Benzoate BP
White Soft Paraffin BP (White Petroleum Jelly)
Parachloro Meta Cresol (Chlorocresol) BP
Propylene Glycol BP
Sodium Dihydrogen Phosphate Dihydrate BP
Carrot Fragrance 290809 IH
Purified Water BP

6.2 Incompatibilities

None

6.3 Shelf life

36 months (3 Years)

6.4 Special precautions for storage

Do not store above 30. Protect from sunlight. Keep out of reach of children. Do not freeze.

6.5 Nature and contents of container

15 gm & 30 gm collapsible aluminium tube.

6.6 Special precautions for disposal and other handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

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Jumeirah Lakes Towers Dubai-UAE.

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8. MANUFACTURER

SHALINA LABORATORIES PVT. LTD.

Manufacturing Site Address:

Shalina Laboratories Pvt. Ltd., Plot No. E-2 & E-3, M.I.D.C., Jejuri, Tal-Purandar, Dist. Pune,
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9. DATE OF REVISION OF TEXT

Every two years.