SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
TRIZEM Cream

2. Qualitative and quantitative composition
Each gram contains: Clotrimazole 1% w/w, Betamethasone Dipropionate 0.05% w/w and Gentamicinsulfate 0.1% w/w.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
A White Cream

4. Clinical particulars
4.1 Therapeutic indications
TRIZEM Cream is used in treating infections of the skin caused by the eczema, contact dermatitis, seborrheic dermatitis, neurodermatitis, tinea corporis, tinea manuum, pedis and corporis.

4.2 Posology and method of administration
FOR EXTERNAL USE ONLY.
Apply the cream to the affected area 2-3 times daily.

4.3 Contraindication
It is contraindicated in patients who are sensitive to clotrimazole, betamethasone dipropionate, other corticosteroids or imidazoles, or to any ingredient in these preparations. And contraindicated in individuals sensitive to its components.

4.4 Special warnings and precautions for use
Avoid contact with eyes, mouth, nose etc.
Do not use in children except under the supervision of adult.
Hypersensitivity to this drug should not use.
Caution should be exercised when used for patients with hypertension, heart disease,osteoporosis and hepatic insufficiency.
Do not use in pregnant or nursing woman except under the advice of doctor. Avoid long time large area use.
Continuous use should not exceed 4 weeks. Continuous use for face, subaxilla, inguinal region and vulva should not exceed 2 weeks. Consult doctor if symptoms were not improved.

4.5 Interaction with other medical products and other forms of interaction
No interaction studies have been performed.

4.6 Pregnancy and lactation
Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit 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.

4.7 Effects on ability to drive and use machines

TRIZEM Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions to TRIZEM 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

Topical Application

Excessive topical application may lead to erythema, oedema and a burning sensation, which willdisappear upon discontinuation of the treatment.

Ingestion

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Topical corticosteroid and anti-infectives in combinationATC Code: D01AC20

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In vitroactivity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci – with the exception of Enterococci – in concentrations of 0.5-10 µg/ml substrate.

Primary resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is

minimally absorbed from intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 µg/ml, suggesting that clotrimazole applied topically in unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity. Clotrimazole 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 clotrimazole 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 24hrs.

6. Pharmaceutical particulars

6.1 List of excipients

Dimethyl Sulfoxide
Cetostearyl Alcohol
Glyceryl Monostearate
Glycerin
Liquid Paraffin
White soft paraffin
Paregal O
Stearic Acid
Trolamine
Carbomer
Butylated Hydroxytoluene
Ethylparaben
Purified Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 30°C in dry place away from sunlight.Protect from light. Keep out of reach of children.

6.5 Nature and contents of container
Collapsible aluminum tube having a screw threaded neck finish sealed with an aluminum membrane. Each tube is supplied with a white polyethylene screw cap which has a piercing tipto puncture open the aluminum membrane on the neck.
Pack size: 10g

6.6 Special precautions for disposal and other handing
No special requirements

7. Name of the Marketing Authorization Holder
Alphaceuticals Limited
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Country: United Kingdom.
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8. Marketing Authorisation Number
TAN 20 HM 0445

9. Date of First Authorisation / Renewal of The Authorisation
25/09/2020

10. DATE OF REVISION / APPROVAL OF THE TEXT