For dermatomycosis

ENDIX Cream 10g

Reg. No. : MAL08082701AZ

■ **Composition :** 1g contains

· Active ingredients

Econazole Nitrate ····· 10mg

Triamcinolone Acetonide ····· 1.0mg

· Preservatives

Methyl paraben 0.1% & Propyl paraben 0.1%

■ **Description :** White cream

■ **Indication**

Dermatophytosis : Tinea pedis (Athlete's foot), Tinea corporis (Ringworm), Tinea capitis, Tinea cruris, Tinea barbae.
Tinea versicolor, Candidiasis, Eczema, Dermatitis, Intertrigo.

■ **Pharmacodynamics**

Econazole nitrate is a broad spectrum antifungal and antibiotic agent, active against dermatophytes (Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum and Malassezia furfur); pathogenic yeasts; Candida albicans and other Candida species. It is also active against gram positive bacteria.
Triamcinolone acetonide is a potent fluorinated corticosteroid with rapid anti-inflammatory, antipruritic and anti-allergic actions.

■ **Pharmacokinetics**

Triamcinolone, when administered by topical application, are well absorbed from sites of local application.
Econazole's absorption is not significant when applied to the skin.

■ **Contraindication**

1. Bacterium (tuberculosis, syphilis), virus (herpes zoster, herpes simplex, chickenpox, vaccinia etc...) infection
2. Patients with hypersensitivity or history to this drug and its ingredients
3. Eczematous otitis externa with perforated eardrum
4. Ulcer (excluding Behcet's disease), burn (exceed secound degree), chilblain
5. Perioral dermatitis, acne vulgaris, rosacea patients
6. Initial stage of skin inflammatory lesion

■ **Interaction**

No significant interaction with other medication

■ **Symptoms & Treatment of Overdose**

If accidental ingestion of Endix Cream occurs, an appropriate method of gastric emptying may be used if considered appropriate.

■ **Dosage and Administration :**

Apply to the affected area once / twice daily

■ **Precaution**

1. Do administer carefully to patients as below
   (1) Pregnancy or female of childbearing potential
   (2) Infant and child
   (3) Because this drug contains propylene glycol, it should be cautiously administered to the patients with history of hypersensitivity or allergic to these components
2. Adverse effects
   (1) Skin
   - Skin infection : Bacterial(infectious impetigo, folliculitis etc) and viral infections may occur
   - Other dermal symptoms : folliculitis, skin irritation, rash · flare, itching, allergic contact dermatitis, pigmentation, urticaria etc. may occur.
   - Long term therapy : xeroderma, steroidal acne, steroidal skin(skin atropy, telangiectasis) and changes of the skin such as thinning, purpura, hirsutism and hypopigmentation may occur. If these symptoms occur, discontinue the therapy

   (2) Endocrine system : long term therapy or occlusive dressing technique(ODT) may cause hypothalamus-pituitary-adrenal(HPA) axis suppression
   (3) Eye : When this drug is used in eyelid skin, ocular hypertension and glaucoma may occur. Cataract and glaucoma might result from long term continuous therapy or occlusive dressings
   (4) Others : Inhibition of endogenous corticoid synthesis, hyperadrenalism with edema, diabetes mellitus, osteoporosis, growth delay for children
3. General precautions
   (1) Follow recommended dose
   (2) In case of any application for a child, consult with doctor and parents.
   (3) Long term continuous therapy, particularly occlusive dressings, should be avoided since it may cause side effects same as systemic administration of corticosteroid.
   (4) If the symptom is not improved or is aggravated, discontinue the therapy
   (5) After the symptom is improved, change this drug to other non-steroidal drugs as soon as possible
   (6) Do not exceed 7 days of treatment
4. Use in pregnancy and lactation
   (1) Embryonic toxicity may occur when administer econazole nitrate(10~40 times of skin dosage for men) orally to rats and similar result occur when administer econazole nitrate(40~80 times of skin dosage for men) orally to mouse, rabbit and rats
   (2) Safety for use of this drug in pregnancy has not yet been established. It should be given to women who are pregnant or pregnant potential only when the expected benefits exceed the risks. Especially, do not use during the first 3 months of pregnancy
   (3) It has not been reported that this drug is excreted in human milk but corticoid which is absorbed systemically excreted in human milk.
5. Infant
   Long term therapy or occlusive dressing technique(ODT) may cause growth delay for infant and child. Using napkin may cause similar effect to occlusive dressing technique(ODT)
6. Caution in application
   Do not use for ophthalmological field

■ **Storage**

Store below 30℃

■ **Dosage Form**

Cream

■ **Packing available**

10g tube individually packed whithin a cardboard box

■ Date of Revision: 10.4.2019

"Jauhi dari kanak-kanak" / Keep out of reach of children
Ubat Terkawal / Controlled Medicine

Manufactured by :

Dongkwang Pharm. Co., Ltd.

115, Sandan-ro, Pyeongtaek-si, Gyeonggi-do, Korea

Name & Address of Importer/Distributor :

Propharm (M) Sdn. Bhd.

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