

COMPOSITION:

Eco Plus[®] Cream : Each gram cream contains Econazole Nitrate BP 10 mg and Triamcinolone Acetonide BP 1 mg.

PHARMACOLOGY:

Eco Plus[®] Cream is a broad spectrum antimycotic with anti-inflammatory, anti-pruritic and anti-allergic effects. This cream is composed of Econazole Nitrate, a powerful antifungal and Triamcinolone Acetonide to enforce its antimicrobial effect and the effect of subduing comprehensive inflammations, therefore, it provides remarkable effects on mixed infections of gram-positive and fungus, eczema and recurrent inflammations and shows special effects on bacterial inflammations of skin folds. The range of action of Econazole covers all dermatomycosis caused by the following pathogens:- *Dermatophytes*, such as *Trichophyton*, *Epidermophyton*, *Microsporum*, *Cladosporium*, *Yeasts*, such as *Candida*, *Cryptococcus neoformans*, *Torulopsis*, *Rhodotorula*, *Moulds*, *Fungi*, such as *Scopulariopsis brevicaulis*, *Aspergillus flavus*, *Histoplasma capsulatum*, *Blastomycosis dermatitidis* and others. As well as *Malassezia furfur* and *Nocardia minutissima*. Moreover, it has antibacterial effect on gram-positive cocci and bacilli, including *Streptococcus pyogenes* and *staphylococcus aureus*. It is also effective against *Trichomonus vaginalis*, *versicolor* and *balanitis*. On the other hand Triamcinolone Acetonide is a synthetic steroid which inhibits not only the early phenomena of the inflammatory process but also the later manifestations.

INDICATION:

Eco Plus[®] Cream is indicated for the treatment of steroid-responsive inflammatory dermatoses with econazole-sensitive mycotic and/or bacterial superinfections like - 1. Eczematous mycosis 2. Eczema marginatum hebecae 3. Herpes circinatum 4. Folliculitis trichophytica 5. Mycosis Barbae 6. Onychomycosis - for the treatment of onychomycosis, local therapy with **Eco Plus[®] Cream**, combined with an oral antimycotic is recommended.

DOSE & ADMINISTRATION:

Adults: **Eco Plus[®] Cream** Apply twice daily to the affected area and rub on the skin gently with the finger. Continue the applications for 14 days or as directed by the Physician.

Children: Suitable for topical application to children.

For topical administration only.

CONTRA-INDICATION:

Not to be used in the treatment of tuberculous lesions and viral diseases of the skin (herpes, vaccinia, Varicella).

WARNING AND PRECAUTION:

For external use only. **Eco Plus[®] Cream** is not for ophthalmic or oral use. If a reaction suggesting hypersensitivity or chemical irritation should occur, use of the medication should be discontinued. Topical corticosteroids may lead to increased risk of dermatological super infection or opportunistic infection. The infected area should be kept clean and dry during treatment.

SIDE EFFECTS:

Rarely, transient local mild irritation, itching & redness may occur immediately after application. **Eco Plus[®] Cream** has minimal allergenic effect and is well tolerated, even by delicate skin. Adrenal suppression on long term continuous topical steroid therapy may occur, particularly in infants or children, or when occlusive dressings are applied. It should be noted that an infant's napkin may act as an occlusive dressing.

USE IN PREGNANCY & LACTATION:

Use in Pregnancy: Not the Econazole but the Triamcinolone Acetonide crosses the placenta and topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids in large amounts or for prolonged periods should not be used in pregnancy.

Use in Lactation: Negligible amount of econazole and to some extent Triamcinolone may be excreted in small amounts in breast milk. So, this cream should not be prescribed to the lactating mother or if prescribed lactation should be withheld during treatment.

USE IN CHILDREN & ADOLESCENTS:

May be use cautiously in children and adolescent or as directed by the physician.

DRUG INTERACTION:

Econazole: is a known inhibitor of CYP3A4/2C9. However, due to the limited systemic availability after cutaneous application, clinically relevant interactions are unlikely to occur but have been reported for oral anticoagulants. In patients taking oral anticoagulants, such as Warfarin or Acenocoumarol, caution should be exercised and the anticoagulant effect should be monitored.

Triamcinolone: Lowering of plasma salicylates levels. Increase risk of GI bleeding and ulceration with NSAIDs. Antagonized blood glucose-lowering effects of the antidiabetics. Increase risk of hyperkalemia with amphotericin B, beta blockers, potassium-depleting diuretics, theophylline Increase clearance of the Triamcinolone with Cyclosporine, Carbamazepine Phenytoin, Barbiturate and Rifampicin. Infection may develop if given with live vaccines.

OVERDOSE:

Eco Plus[®] Cream is intended for topical use. If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered desirable.

STORAGE:

Store in a dry and cool place below 30^o C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Eco Plus[®] Cream: Each box contains 10 gm cream in a tube.



Manufactured by

Team Pharmaceuticals Ltd.

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