

BW14UM-221228

Title: BioWell Bconazine Cream - PI

Date: 28 December 2022

BioWell BCONAZINE CREAM

Active Ingredients:

Econazole Nitrate 1.0%/w/w
Triamcinolone Acetonide 0.1%/w/w

Preservative:
Chlorocresol 0.1%/w/w

Presentation:

Tube of 15g.

Product Description:

White smooth cream.

Pharmacology: BioWell Bconazine Cream is a combination of broad spectrum antimycotic, Econazole Nitrate and topical corticosteroid, Triamcinolone Acetonide with anti-inflammatory, antipruritic and antiallergic effects. Econazole Nitrate is an imidazole antifungal agent which acts against dermatophytes (*Trichophyton*, *Epidermophyton*, *Microsporum*, *Pityrosporum*); pathogenic yeast (*Candida albicans* and other candida species) and moulds. The compound acts by damaging the membranes of bacterial and fungal cells; both the cellular and sub-cellular membranes are affected. Econazole apparently disturbs the permeability characteristic of the membrane which allows leakage of potassium and sodium ions and other intra cellular components. It is also active against Gram positive bacteria, eg. *Staphylococci*, *Streptococci*, *Bacillus anthracis* and *Bacteroides fragilis*.

Triamcinolone Acetonide is a high potency glucocorticoid used as anti-inflammatory or immunosuppressive agents. It has a high lipid-water distribution coefficient which favours penetration into the skin and is thus suitable for topical use. It is employed for the treatment of various sensitive inflammatory and allergic dermatoses.

Econazole is applied topically to the skin. It is not for ophthalmic use. Following topical application, systemic absorption is extremely low. Although most of the applied drug remains on the skin surface, drug concentrations found in the stratum corneum greatly exceed the MIC for dermatophytes. Inhibitory concentrations are achieved in the epidermis and as deep as the middle region of the dermis. Use of an occlusive dressing appears to only slightly increase the extent of dermal penetration of the drug. Less than 1% of an applied dose is recovered in urine and feces.

Bioavailability of Triamcinolone following topical application is dependent on the condition of the skin at the application site. Absorption of topical preparations is increased in areas of skin damage, inflammation, or occlusion, or where the stratum corneum is thin such as the eyelids, genitalia and face. Topical preparations of Triamcinolone are metabolized in the skin, and systemic Triamcinolone is metabolized by the liver to inactive metabolites. These inactive metabolites, as well as a small portion of unchanged drug, are excreted in the urine.

Indications: BioWell Bconazine Cream is indicated for the treatment of dermatomycoses complicated by inflammatory and/or pruritic manifestations of skin disorders.

Directions of Use: Cream for topical application to the skin. BioWell Bconazine Cream should be applied to the affected area no more than 2 times daily, preferably once in the morning and once in the evening. BioWell Bconazine Cream should not be applied with an occlusive dressing, or to large skin areas of the body.

The duration of treatment with the BioWell Bconazine Cream should be until the inflammatory symptoms subside but no longer than 2 weeks; after 2 weeks of therapy with BioWell Bconazine Cream, continue therapy as needed with a preparation containing econazole or econazole nitrate alone.

Symptoms and Treatments of Overdose: Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. No specific antidote is available. In the event of accidental ingestion, the patient should be observed and treated symptomatically.

Mode of Administration: Topical use.

Contraindications: Contraindicated in cases of tuberculous, luetic or virus infections (herpes, vaccinia, varicella) of the skin or varicose veins. Do not use if hypersensitivity to imidazole or corticosteroids.

Precautions: For external use only. Avoid in contact with eyes, nose and mouth. Not to be taken. Avoid prolonged application to the face. Avoid occlusive dressing to large areas of the body because of the increased risk of systemic absorption. If symptoms persist, please consult a doctor.

Use in Pregnancy and Lactation: Safety in pregnancy has not been established. Econazole should not be used in pregnant women or in those likely to become pregnant unless the expected benefit outweighs the potential risk. It is not known whether Econazole is excreted in breast milk or whether it has a harmful effect on the new born. However as systemic absorption is low in humans, any excretion into breast milk is likely to be low.

Interactions with Other Medicaments: Do not use any other skin products on the affected area without consulting your doctor or health professional.

Undesirable Effects: Occasionally, skin sensitivity may happen in some sensitive people. Local reactions including slight burning sensation and irritation have been reported.

Storage: Store below 30°C. Protect from light. Keep cap tightly closed. Keep out of reach of children. *Jauhkan daripada capaian kanak-kanak.*

Shelf Life: 2 years from the date of manufacture.

Registration No.: MALxxxxxxxAZ

A,ES|BZ-1,01

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Product Registration Holder
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Size: 75mm x 115mm

■ Dark Blue (Pantone 2767U)