**SEZO-B**
**Sertaconazole Nitrate and Beclomethasone Cream**

**COMPOSITION:**

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| Sertaconazole Nitrate | BP | 2.0 % w/w |
| Beclomethasone Dipropionate | USP | 0.025% w/w |
| Cream Base | | q.s. |

**DESCRIPTION:**
Sertaconazole is an antifungal that belongs to the imidazole class of antifungal agents. Beclomethasone dipropionate is a synthetic halogenated corticosteroid with potent glucocorticoid activity but weak mineralocorticoid activity.

**PHARMACODYNAMIC:**
**Sertaconazole Nitrate**
Sertaconazole is an antifungal that belongs to the imidazole class of antifungals and exhibits activity similar to that of other imidazoles. It is believed that they act primarily by inhibiting the cytochrome (CY) P450dependent synthesis of ergosterol. Ergosterol is a key component of the cell membrane of fungi, and lack of this component leads to fungal cell injury, primarily by leakage of key constituents in the cytoplasm from the cell.In clinical infections, sertaconazole nitrate has been shown to be active against isolates of dermatophytes (e.g. Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton occosum). Additionally, sertaconazole has demonstrated a broad spectrum of antifungal activity both in vitro and in experimental in vivo models, which includes opportunistic filamentous fungi (e.g. Aspergillus, Alternaria, Scopulariopsis, Fusarium), and pathogenic yeasts such as Malassezia furfur, Candida albicans, Candida tropicalis, Torulopsis, and Trichosporon. Activity has also been observed against Trichomonas and some Gram-positive organisms (staphylococci, streptococci).
**Beclomethasone Dipropionate**
Like other topical corticosteroids, beclomethasone dipropionate has anti-inflammatory, antipruritic and vasoconstrictive actions. The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase-A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase-A2. Beclomethasone is rapidly degraded enzymatically to a less active metabolite, significantly diminishing the possibility of systemic toxicity.

**PHARMACOKINETIC:**
Sertaconazole achieves high epidermal concentrations following cutaneous application. Cutaneous absorption was 64% of the dose at 12 hours and 72% at 24 hours following topical application of a 2% cream. Systemic absorption is minimal to undetectable. The drug was undetectable in serum or urine samples from healthy subjects for up to 24 hours with 16 g of sertaconazole nitrate cream,2%.
Beclomethasone is stated to be readily absorbed from sites of local application, and rapidly distributed to all body tissues. It is metabolized principally not only in the liver but also in other tissues, including the gastrointestinal tract and lungs; enzymatic hydrolysis rapidly produces the monopropionate and more slowly, the free alcohol, which is virtually devoid of activity. Only a small proportion of an absorbed dose is excreted in the urine, with the remainder being excreted in the faeces mainly as metabolites. When applied topically, particularly to large areas,when the skin is broken or under occlusive dressings, corticosteroids like beclomethasone may be absorbed in sufficient amounts to cause systemic effects.

**INDICATION:**
For the topical treatment of fungal infections of skin with eczematous features.

**DOSAGE AND ADMINISTRATION:**
Clean and dry the affected areas thoroughly before application of SEZO-B Cream. Apply sufficient quantity of SEZO-B Cream to the affected skin areas twice daily. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

**CONTRAINDICATION:**
SEZO-B Cream is contraindicated in patients with a history of hypersensitivity to sertaconazole nitrate, beclomethasone dipropionate or any other component of the formulation.

**SPECIAL WARNING AND PRECAUTION FOR USE:** Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, with the potential for glucocorticoid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycaemia and glucosuria can also be produced in some patients by the systemic absorption of topical corticosteroids while on treatment.Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the Adrenocorticotropic hormone (ACTH) stimulation, A.M. plasma cortisol, and urinary-free cortisol tests. Patients receiving super-potent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression. If 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. Infrequently, signs and symptoms of glucocorticoid insufficiency may occur, requiring supplemental systemic corticosteroids. Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratio.
It should also be avoided in patients with the following:
- History of allergic type responses to other topical or oral corticosteroids (enhanced risk of sensitivity).
- Evidence of pre-existing skin atrophy (exacerbation).
- Diabetes mellitus (potential hyperglycaemic action of topical steroid if there is sufficient absorption).
- Glaucoma or cataracts (potential worsening if there is sufficient absorption of topical steroid).
- Pregnancy or breastfeeding period (safety not clearly established).
- Liver failure as it may cause HPA axis suppression, Cushing's syndrome, hyperglycaemia or glycosuria.
- Active viral illnesses such as chicken pox or measles as a topical steroid may increase the risk of serious or fatal infection.

**INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:**
Potential interactions between sertaconazole nitrate cream, 2%, and other drugs or laboratory tests have not been systematically evaluated. There are no reports of drugs interacting with topical beclomethasone dipropionate.

**PREGNACY & LACTATION:**
**Pregnancy**
Animal reproduction studies of topical steroids have shown an adverse effect on the foetus and there are no adequate and wellcontrolled studies in humans, but the potential benefits may warrant use of the drug in pregnant women despite the potential risks.There are no adequate and well-controlled studies that have been conducted on topically applied sertaconazole nitrate cream, 2%, in pregnant women. Because animal reproduction studies are not always predictive of human response, sertaconazole nitrate cream, 2%, should be used during pregnancy only if clearly needed. The safety and efficacy of sertaconazole nitrate and beclomethasone dipropionate cream has not been established in pregnant women.SEZO-B Cream is not recommended in pregnant women.
**Lactation**
There is no clinical data available regarding the excretion of either sertaconazole nitrate or beclomethasone in breast milk. No effects on the lactating child are anticipated since the systemic exposure of the breastfeeding woman to sertaconazole nitrate or beclomethasone dipropionate is negligible following topical application. The use of SEZO-B Cream is not recommended in breastfeeding mothers.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:**
No studies on the effects on the ability to drive and use machines have been performed.

**UNDESIRABLE EFFECT:**
- Skin tenderness
- Mild rash
- Dry skin
- Skin bruising
- Itching
- Irritation
- Redness
- Stinging or burning sensation

**OVERDOSE:**
Topically applied sertaconazole nitrate and beclomethasone dipropionate cream may be absorbed in sufficient amounts to produce systemic effects. Excessive prolonged use of topical corticosteroids can suppress the pituitary adrenal function, resulting in secondary adrenal insufficiency. Appropriate symptomatic treatment is indicated in the event of overdosage.Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance if necessary. In cases of chronic toxicity,slow withdrawal of corticosteroids is advised.

**INCOMPATIBILITY**
Not applicable

**SHELF LIFE:**
36 months

**PACKAGING**
10 gm laminated tube with tray is packed in a printed carton along with pack insert.

**STORAGE CONDITION:**
Store in a cool & dry place. Protect from light & moisture. Do not freeze.
**Keep out of reach of children.**
Avoid contact with eyes.
Keep the tube tightly closed after use.
**FOR EXTERNAL USE ONLY.**

***Product of***

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