

## CLOTRINE B

**For use by a Registered Medical Practitioner or Hospital or a Laboratory only.**

### **CLOTRINE-B CREAM.**

For topical application .

### **COMPOSITION:**

Contains 1% w/w Clotrimazole BP and Betamethasone 0.05% w/w (as Betamethasone dipropionate BP).

### **DESCRIPTION:**

Clotrine-B cream contains a combination of Clotrimazole, a synthetic antifungal agent, and Betamethasone dipropionate, a synthetic corticosteroid, for dermatological use.

### **CLINICAL PHARMACOLOGY:**

Clotrine-B has Betamethasone dipropionate, a compound with anti-inflammatory, antipruritic and vasoconstrictive properties, combined with Clotrimazole, a broad spectrum antifungal agent.

Clotrimazole has its primary action against dividing and growing organisms. It interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. It interferes with fungal DNA replication by binding sterols in fungal cell membrane which increases permeability and causes leaking of nutrients.

The mechanism of anti-inflammatory activity of Betamethasone is generally unclear. However, it is thought to act by induction of phospholipase  $A_2$  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  $A_2$ .

### **PHARMACOKINETICS:**

Synthetic corticosteroids are extensively bound to plasma proteins mainly globulin and less to albumin .

The corticosteroid binding globulin has high affinity but large binding capacity. They also have long half life. Betamethasone dipropionate is metabolized mainly in the liver, but also in the kidney and excreted in the urine.

When Clotrimazole is applied topically, it penetrates the epidermis but there is little if any systemic absorption. Six hours after the application of clotrimazole 1% cream onto intact and actually inflamed skin, the concentration of Clotrimazole varies from 100 mcg/cm<sup>2</sup> in the stratum corneum to 0.5 to 1 mg /cm<sup>2</sup> in the stratum reticulare and 0.1 mcg/cm<sup>2</sup> in the subcutis. Only 0.5% or less of the applied clotrimazole is excreted in the urine.

### **INDICATIONS:**

Clotrine-B cream is indicated for the treatment of the following conditions where secondary corticosteroid responsive dermatoses is present, suspected or likely to occur, *Tinea cruris* and *Tinea corporis* due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum* and *Microsporum canis*. Betamethasone dipropionate in the combination is effective against corticosteroid - responsive dermatoses primarily because of its anti-inflammatory, antipruritic and vasoconstrictive actions.

These include eczema, including atopic, infantile and discoid eczemas, prurigo, psoriasis (excluding widespread plaque psoriasis), neurodermatoses, including *lichen planus*, *seborrhoeic dermatitis*, *intertrigo*, contact sensitivity reaction, *discoid lupus erythematosus*.

Clotrimazole on the other hand is effective against all dermatomycoses due to dermatophytes (e.g. *Trichophyton species*), of yeasts (candida species), or moulds and other fungi. So Clotrine-B is indicated where the above dermatoses are showing super infections with these fungi.

### **CONTRAINDICATIONS:**

Clotrine-B cream is contraindicated in patients who are sensitive to either or both of the active ingredients or to other imidazoles or corticosteroids.

### **PRECAUTIONS:**

Systematic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression manifestation of cushing's syndrome, hyperglycemia and glycosuria in some patients.

If local irritation develops, the use of the cream should be discontinued and appropriate therapy instituted as necessary.

Patients should be advised to use the cream for the fully prescribed treatment, even though the symptoms may have improved and to notify the physician if there is no improvement after one week of treatment for *Tinea cruris*, *Tinea corporis*, or after two weeks of *Tinea pedis*.

Patients should be advised that the treated skin area should not be bandaged or otherwise covered or wrapped as to be occluded, and to report any signs of local adverse reactions.

Clotrine-B should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus because potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

**Children:** Safety and effectiveness of Clotrine-B in pediatric patients has not been established. Use in children under 12 years of age is not recommended.

### **ADVERSE REACTIONS:**

Paresthesia, maculopapular rash, edema and secondary infection have been reported.

Irritation, allergic contact dermatitis, itching, dryness, skin atrophy etc. have been reported.

### **DOSAGE AND ADMINISTRATION:**

Gently massage sufficient Clotrine-B cream into the affected and surrounding skin areas twice a day, in the morning and evening for two weeks in *Tinea cruris* and *Tinea corporis*, and for 4 weeks in *Tinea pedis*.

### **PRESENTATION:**

Packed in 15g and 30g in collapsible aluminium tubes packed in unit boxes.

### **STORAGE:**

Do not store above 30°C. Keep tightly closed. Protect from heat. Keep all medicine away from children.

Manufactured by:

**UNIVERSAL**  
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SIZE: 120X160MM