

### **1.3 Product Information**

#### **1.3.1 Summary of Product Characteristics (SmPC):**

**1. NAME OF THE MEDICINAL PRODUCT:**

**WINBACT** (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION:**

**Composition:**

- Betamethasone Dipropionate USP Eq. to Betamethasone (0.05 % W/W)
- Neomycin Sulfate USP (0.5 % W/W)
- Clotrimazole USP (1.0 % W/W)
- Cream Base (- QS)

**3. PHARMACEUTICAL FORM: TOPICAL CREAM**

A white to off-white smooth cream.

**4. CLINICAL PARTICULARS:**

**4.1 Therapeutic indications:**

**WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream)** provides a comprehensive treatment for various inflammatory dermatological disorders superseded with bacterial or superficial fungal infections of the skin. Betamethasone Dipropionate is one of the most potent topical corticosteroids available and rapidly controls the symptoms such as itching, redness and scaling.

Many times, the inflammatory skin disorders which respond to topical corticosteroids are superadded with bacterial and / or fungal infections of the skin. In these conditions, treatment with anti-inflammatory agents alone is not sufficient and a proper antibiotic has to be added in the regimen.

Clotrimazole is a broad spectrum synthetic antifungal agent which has fungicidal action against all the fungi responsible for superficial fungal infections of skin. Neomycin sulphate is broad spectrum antibacterial, antibiotic. Hence **WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream)** effectively controls inflammatory disorders superadded with bacterial and / or fungal infections of the skin.

**4.2 Posology and method of administration**

**WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream)** should be thinly and evenly applied to the affected area two to three times a day with a gentle rub.

**Method of Administration:** For topical application.

#### **4.3 Contraindications**

**WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream)** is contraindicated in individuals having hypersensitivity to Clotrimazole, Neomycin Sulfate and Betamethasone Dipropionate.

#### **4.4 Special warnings and precautions for use**

**WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream)** should not be used with occlusive dressings.

If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided, particularly in infants and children where adrenal suppression may occur even without occlusion.

If irritation or sensitisation develop, treatment should be discontinued, and appropriate remedial therapy instituted.

In the presence of bacterial or viral infection, an appropriate antibacterial or antiviral agent should be administered concurrently. If response does not occur promptly, WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream) should be discontinued until the infection has been controlled adequately.

Systemic absorption of topical corticosteroids will be increased if extensive body surface areas or skin folds are treated.

Suitable precautions should be taken under these conditions or when long term use is anticipated, particularly in infants and children.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

Hypothalamic-pituitary adrenal axis suppression. Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilla-edema.

The safety and effectiveness of WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream) in children below the age of 12 has not been established.

WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream) is not intended for ophthalmic use.

**4.5 Interaction with other medicinal products and other forms of interaction:** None reported.

#### **4.6 Fertility, pregnancy and lactation**

Studies in animals have shown a teratogenic effect. To date no such effects have been reported in human beings during pregnancy or lactation. However, this product should not be used in pregnancy or lactation unless considered essential by the physician. It is not known whether the components of WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream) are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

#### **4.7 Effects on ability to drive and use machines**

The medicinal product has no influence on the ability to drive or operate machinery

#### **4.8 Undesirable effects**

Adverse reactions reported for WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream) include : burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone Dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria, capillary fragility (ecchymoses) and sensitization.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

Delayed type hypersensitivity reactions have been reported during use of neomycin; sensitization has been reported following prolonged use. Ototoxicity and nephrotoxicity have been reported when applied to large surfaces or damaged skin.

#### **4.9 Overdose**

Acute overdosage with topical application of WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream) is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of WINBACT CREAM (Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream). Accidental ingestion should be treated symptomatically.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

**ATC Code:** D07AC01, D01AC20 & D06AX04

**Pharmacotherapeutic group:** Antifungal, Antibacterial, Anti inflammatory

Betamethasone Dipropionate is one of the most potent topical corticosteroids available and rapidly controls the symptoms such as itching, redness and scaling.

Many times, the inflammatory skin disorders which respond to topical corticosteroids are superadded with bacterial and / or fungal infections of the skin. In these conditions, treatment with anti-inflammatory agents alone is not sufficient and a proper antibiotic has to be added in the regimen.

Clotrimazole is a broad spectrum synthetic antifungal agent which has fungicidal action against all the fungi responsible for superficial fungal infections of skin. Neomycin sulphate is broad spectrum antibacterial, antibiotic.

### **5.2 Pharmacokinetic properties**

#### **1. Betamethasone Dipropionate:**

Topical: -

Absorption: It is absorbed in to the systemic circulation and the amount is depending on the potency, amount applied and the nature of the skin at the site of application. Absorption increases at the site of skin damage, inflammation or occlusion.

#### **2. Neomycin Sulfate:**

Neomycin can be absorbed through inflamed skin. Once absorbed, it is rapidly excreted unchanged through the kidneys. The half-life is approximately 2 to 3 hours.

#### **3. Clotrimazole:** Absorption is minimal after topical administration.

### **5.3 Preclinical safety data**

Not applicable.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Cetomacrogol 1000

Cetostearyl Alcohol

White Soft Paraffin

Sodium Acid Phosphate

Chlorocresol

Light Liquid Paraffin

Propylene Glycol

Perfume Dream Touch MGL 17286

Purified Water

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

36 months

## **6.4 Special precautions for storage**

Store at temperature not exceeding 30°C; do not freeze.

## **6.5 Nature and contents of container**

A 30gm lami tube is packed in printed inner carton along with leaflet.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7. Marketing authorization holder**

**Kremoint Pharma Private Limited,**

B-8 Additional MIDC, Ambernath

Ambernath (E). Thane 421506,

## **8. Marketing authorization number(s):**

28-KD/146

## **9. Date of first authorization/renewal of the authorization**

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## **10. Date of revision of the text:**

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