

## **Prescribing Information (Summary of Product Characteristics)**

### **1. Name of the medicinal product**

Laeotarin Cream.

### **2. Qualitative and quantitative composition**

**Laeotarin cream contains:** Miconazole Nitrate BP 2% w/w.

### **3. Pharmaceutical form**

#### **Topical use.**

White semi-solid, non-gritty cream. Packed in 15g collapsible tubes and contained in a unit box along with literature insert.

### **4. Clinical particulars**

#### **4.1 Therapeutic indications.**

Laeotarin cream is applied in the treatment of tinea pedis (athlete's foot), tinea cruris and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes* and *Epidermophyton floccosum*. It is also used in the treatment of cutaneous candidiasis (moniliasis) caused by *Candida albicans* and in the treatment of tinea versicolor caused by *Malassezia furfur*.

#### **4.2 Posology and method of administration**

Laeotarin is applied topically on the affected areas twice daily (morning and evening) in patients with tinea pedis, tinea cruris, tinea corporis, cutaneous candidiasis and once daily in patients with tinea versicolor. It is recommended that when the preparation is used in intertriginous areas, it should be applied sparingly and smoothed-in well to avoid maceration effects. Early relief of symptoms (2 to 3 days) is experienced by the majority of the patients and clinical improvement may be seen fairly soon after treatment is begun; however, candida infections and tinea cruris and corporis should be treated for two weeks and tinea pedis for one month in order to reduce the possibility of recurrence. If a patient shows no clinical improvement after one month of treatment, the diagnosis should be re-determined.

Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

#### **4.3 Contraindications**

Laeotarin cream is contraindicated in individuals with a known hypersensitivity to miconazole/miconazole nitrate, other imidazole derivatives or to any of the excipients listed in section 6.1.

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

Store in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

#### **Paediatric population**

Not applicable

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after topical application, clinically relevant interactions are rare. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored.

#### **Additional information on special populations**

Not applicable

#### **Paediatric population**

No additional information

#### 4.6 Fertility, Pregnancy and lactation

##### Pregnancy:

In animals miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are absorbed following topical administration. However, as with other imidazoles, miconazole nitrate should be used with caution during pregnancy.

##### Breast-feeding:

Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation.

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

Not relevant.

#### 4.8 Undesirable effects

Adverse drug reactions reported among 834 patients who received miconazole 2% cream (n=426) and/or placebo cream base (n=408) in 21 double-blind clinical trials are presented in Table 1 below. Moreover, adverse drug reactions from spontaneous reports during the worldwide post-marketing experience with Miconazole that meet threshold criteria are included in Table 1. The adverse drug reactions are ranked by frequency, using the following convention:

Very common  $\geq 1/10$

Common  $\geq 1/100$  and  $< 1/10$

Uncommon  $\geq 1/1,000$  and  $< 1/100$

Rare  $\geq 1/10,000$  and  $< 1/1,000$

Very rare  $< 1/10,000$ , including isolated reports

Adverse reactions obtained from clinical studies and post-marketing surveillance are presented by frequency category based on incidence in clinical trials or epidemiology studies, when known.

**Table 1: Adverse reactions reported in clinical trials and post-marketing experience**

System Organ Class	Adverse Reactions	
	Frequency Category	
	Uncommon ( $\geq 1/1,000$ to $< 1/100$ )	Not known
Immune System Disorders		Anaphylactic reaction Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Skin burning sensation Skin inflammation Skin hypopigmentation	Angioedema Urticaria Contact dermatitis Rash Erythema Pruritus
General Disorders and Administration Site Conditions	Application site irritation Application site burning Application site pruritus Application site reaction NOS Application site warmth	

## **4.9 Overdose and treatment**

### Symptoms

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

### Treatment

Miconazole cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

**Pharmacotherapeutic classification:** (Antifungals for dermatological/topical use; imidazole derivative)

**ATC code:** D01A C02.

Miconazole cream is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity.

### **5.2 Pharmacokinetic properties**

**Absorption:** There is little absorption through skin or mucous membranes when miconazole is applied topically.

**Distribution:** Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).

**Metabolism and Excretion:** The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.

### **5.3 Preclinical data safety**

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

- Chlorocresol
- Cetostearyl Alcohol
- Cetomacrogol 1000
- White Soft Paraffin
- Liquid Paraffin
- Sodium Dihydrogen Phosphate

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 Months from the date of manufacture.

### **6.4 Special precautions for storage**

Keep in a dry place below 30°C.

Do not freeze. Protect from light.

Keep all medicines out of reach of children.

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

An aluminium collapsible tube with Lavender blush and green colour printed in white and black with a threaded mouth and sealed top.

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

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:**

**Company Name:** LABORATORY & ALLIED LTD

**Address:** Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,  
P.O. Box 42875 GPO 00100, Nairobi,

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**E-Mail:** info@laballied.com

## **8. Marketing Authorization Number:**

**Kenya:** PPB/H99/390

## **9. Date of first Registration/ Renewal of the Registration:**

**Kenya:** 9/12/1999

**Renewal:** Retained annually.

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

**February 2024.**