

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

### **1. Name of the Finished Pharmaceutical Product.**

Labesten Cream.

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

Contains Clotrimazole BP 1% w/w and Chlorocresol as a preservative and excipients in section 6.1.

### **3. Pharmaceutical form.**

Cream.

White semi solid, non-gritty cream.

### **4. Clinical particulars.**

#### **4.1 Therapeutic indications**

Labesten® cream is indicated for the treatment of skin and fungal infections caused by or associated with pathogens sensitive to Clotrimazole therapy. For the treatment of candida vulvitis, adjunct to the treatment of candida vaginitis. Also used for the treatment of candida balanitis of the sexual partner.

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

##### **Adults:**

Over 16 and under 60 years old: apply to the affected area two to three times daily.

Candida infections: treat for at least two weeks.

##### ***Route of administration***

For cutaneous use, for the treatment of candida vaginitis and candida balanitis. Cream to be applied to the vulva and surrounding area. It can also be applied to the sexual partner's penis.

#### **4.3 Contraindications.**

Labesten® cream is contraindicated in patients with known hypersensitivity to Clotrimazole or any of the excipients in the formulation.

#### **4.4 Precautions, Warnings and Side effects.**

- a) Labesten cream is contraindicated in patients with known hypersensitivity to clotrimazole.
- b) Local reactions including irritation and burning sensation, in addition to contact allergic dermatitis may occur in some patients treated topically and in such cases the medication should be discontinued immediately.

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

No interactions have been reported for topical Clotrimazole.

#### **4.6 Pregnancy and lactation.**

##### **Pregnancy:**

There is a limited amount of data from the use of Clotrimazole in pregnant women. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

##### **Lactation:**

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

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

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

#### **4.8 Undesirable effects.**

Immune system disorders: allergic reaction (syncope, hypotension, dyspnea, urticaria).

Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

#### **4.9 Overdose**

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favorable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of Clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

## **5. Pharmacological properties.**

### **5.1 Pharmacodynamic properties.**

Pharmacotherapeutic group: **Antifungals for topical use – imidazole and triazole derivatives.**

ATC code: **D01A C01**

Labesten Cream contains clotrimazole; an imidazole antifungal agent which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. On topical application, clotrimazole penetrates the epidermis but there is little, if any systemic absorption, although slight absorption has been reported following administration on mucus membrane.

### **5.2 Pharmacokinetic properties**

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

### **5.3 Preclinical safety data.**

Not applicable.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Chlorocresol.

Cetomacrogol 1000.

Cetostearyl Alcohol.

White Soft Paraffin.

Liquid Paraffin.

Sodium Dihydrogen Phosphate.

Monopropylene glycol.

Purified water.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 Months

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

Store in a dry place below 30°C; Do not freeze, Protect from light.

Keep all medicine out of reach of children.

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

Filled in 20G in a collapsible tube and packed in a unit box with literature insert.

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

Any unused medicinal 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,

**Country:** Kenya.

**Telephone:** +254 20 8040306

**Telefax:** +254 20 8040309

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

**Manufacturing Site Address:**

**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,

**Country:** Kenya.

**Telephone:** +254 20 8040306

**Telefax:** +254 20 8040309

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

**8. Marketing Authorization Number:**

Kenya: H92/009

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

Date of first Registration: **Kenya: 15/12/1994.**

Renewal of the Registration: **Retained Annually.**

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

March 2024.

**11. Dosimetry (if applicable)**

Not Applicable.

**12. Instructions for preparation of radiopharmaceuticals (if applicable)**

Not Applicable.