

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Lloydspharmacy Antifungal Skin Cream  
Clotrimazole 1% w/w Cream  
Boots Antifungal Cream  
Tesco Antifungal Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole 1% w/w

## 3 PHARMACEUTICAL FORM

Cream

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the treatment of skin infections due to dermatophytes (e.g. trycophyton species), yeasts (e.g. candida species), moulds and other fungi. These include ringworm (tinea) infections, paronychia, pityriasis versicolor, erythrasma and intertrigo, as well as fungal nappy rash, candidal vulvitis and candidal balanitis.

### 4.2 Posology and method of administration

Dosage:

Adult, children and elderly:

Apply to the affected area two or three times daily

Dermatophyte infections: treat for at least one month

Candida infections: treat for at least two weeks

Route of administration:

Directly applied to the affected area.

A physician should be consulted if symptoms do not improve within 7 days.

### **4.3 Contraindications**

Known hypersensitivity to any of the components

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

The cream contains cetyl alcohol and stearyl alcohol, which may cause local skin reaction (e.g. contact dermatitis).

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

Clotrimazole Cream may cause damage to latex contraceptives. Consequently patient should be advised to use alternative precautions for at least five days after using this product.

### **4.6 Pregnancy and lactation**

#### Pregnancy

Data on a large number of exposed pregnancies indicate no adverse effects of Clotrimazole on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

#### Breast-feeding

It is unknown whether clotrimazole is excreted in breast milk, so it should be given with caution to lactating mothers.

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

None known

### **4.8 Undesirable effects**

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

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

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

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## 4.9 Overdose

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). It should be carried out only if the airway can be protected adequately.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

ATC code: D01A C01

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity. It also exhibits activity against *Trichomonas*, staphylococci, streptococci and *Bacteroides*. It has no effect on lactobacilli.

#### Mechanism of action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

#### Pharmacodynamic effects

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In-vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

### 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

There are no preclinical data of reference to the prescriber which are additional to the information included in other sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sorbitan stearate  
Polysorbate 60  
Cetyl Palmitate  
Stearyl Alcohol  
Cetyl Alcohol  
2-Octyldodecanol  
Benzyl Alcohol  
Purified Water

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

36 months

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

None

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

Aluminium tube with polypropylene screw-on cap containing 20/30/50g of cream.

### **6.6 Special precautions for disposal**

None

## **7 MARKETING AUTHORISATION HOLDER**

Teva UK Limited  
Brampton Road  
Hampden Park

Eastbourne  
East Sussex  
BN22 9AG

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00289/1490

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

27 January 1998 / 08 April 2003

**10     DATE OF REVISION OF THE TEXT**

02/07/2015