SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole 1% w/w

Excipient(s) with known effect:

Each 100 mg contains 1 mg benzyl alcohol.

Each 100 mg contains 5 mg cetyl alcohol and 5 mg stearyl alcohol.

For the full list of excipients, see section 6.1.

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

Instruct patients not to smoke or go near naked flames - risk of severe burns.
Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.
Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipient(s)

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

Benzyl alcohol
Benzyl alcohol may cause allergic reactions.
Benzyl alcohol may cause mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Clotrimazole Cream may cause damage to latex contraceptives. Consequentially patients 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. Clotrimazole may be used during lactation. If used topically on the nipple area, wash breasts before feeding child.

Fertility:
No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

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

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)

Vascular disorders: syncope, hypotension.

Respiratory, thoracic and mediastinal disorders: dyspnoea.

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

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 Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. 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.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

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

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs..

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,

Ridings Point,

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WF10 5HX,

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8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/1490

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 January 1998

Date of latest renewal: 08 April 2003

10 DATE OF REVISION OF THE TEXT

22/11/2023