

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lloydspharmacy Athletes Foot Cream
Clotrimazole 1% w/w cream
Tesco Athlete's Foot Cream
Superdrug Athlete's Foot 1% w/w Cream
Wilko Athlete's Foot 1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole 1% w/w

Excipient(s) with known effect:

Each 100 milligrams contains 1 mg benzyl 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 tinea pedis (athlete's foot)

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

Route of administration:

Directly applied to the affected area.

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

If the feet are infected they should be washed and dried, especially between the toes, before applying the cream.

There is no separate dosage schedule for the young or elderly.

4.3 Contraindications

Known hypersensitivity to any of the components

Do not use the cream to treat nail or scalp infections.

4.4 Special warnings and precautions for use

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

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. 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. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects.

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, discomfort/pain, oedema, irritation, peeling/exfoliation, pruritus, rash, urticaria, stinging skin /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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

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.

5.2 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,
Whistler Drive,
Castleford,
WF10 5HX,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/1643

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

27 January 1998

10 DATE OF REVISION OF THE TEXT

17/11/2023