Summary of Product Characteristics

1. Name of the medicinal Product

Clotrimazole Cream BP 1% w/w

2. Qualitative and Quantitative Composition

Each tube contains 1% w/w Clotrimazole

Excipient with known effect: Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Cetostearyl alcohol.

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Cream

A white colour smooth cream filled in aluminium collapsible tube.

4. Clinical Particulars

4.1 Therapeutic Indications

Clotrimazole 1% Cream is recommended for the treatment of All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species).

All dermatomycoses due to yeasts (Candida species).

Skin diseases showing secondary infection with these fungi.

Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and Method of Administration

Adults:

The cream should be applied thinly 2-3 times daily and rubbed in gently. Treatment should be continued for at least one month for dermatophyte infections and at least two weeks for candida! infections.

Elderly: Refer to adult dosing.

4.3 Contraindications

Hypersensitivity to clotrimazole or any other ingredient in this medicine.

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

4.4 Special Warnings and Special Precautions for Use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).
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.

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 Fertility, Pregnancy and Lactation

Pregnancy: There is a limited amount of data from the use ofclotrimazole in pregnant women.
Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.
Lactation: It is not known whether this drug is excreted in human milk, caution should be exercised when clotrimazole is used by a nursing woman.
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 an accurate frequency of occurrence for each is not possible.

Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity.

Vascular disorders: syncope, hypotension.

Respiratory, thoracic and mediastinal disorders: dyspnoea.

Skin and subcutaneous tissue disorders: blisters, dermatitis contact, erythema, parasthesia, skin exfoliation, pruritus, rash, urticaria, stinging skin/burning sensation skin.

General disorders and administration site conditions: application site irritation, application site reaction, oedema, pain.

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 TMDA ADR reporting tool; website: https://imis.tmda.go.tz/arrt or search for TMDA Adverse Reactions Reporting Tool in the Google Play 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.

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

5.1Pharmacodynamics Properties

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

ATC code: D01A C01

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.

Clotrimazole is an imidazole derivative with a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. Clotrimazole acts against fungi by inhibiting ergosterol synthesis.
Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.
The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection.

5.2 Pharmacokinetic Properties

Absorption: Clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation.

Time to peak, serum: Vaginal cream: approximately 24 hours.
Excretion: Clotrimazole appears to be largely excreted in the feces, primarily via biliary excretion. Renal excretion accounts for 0.05% to 0.5% of drug elimination.
Half life: The elimination half life of parent compound is 3.5 to 5 hours.

5.3 Preclinical Safety Data

Preclinical data reveal no special hazard for humans based on conventional studies of local or systemic toxicity, mutagenicity, carcinogenicity and toxicity reproduction.

6 Pharmaceutical Particulars

6.1List of Excipients
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Cetosteryl Alcohol
Cetomacrogol 1000 Light Liquid
Paraffin
White Soft Parafin Phosphoric Acid
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life
36 Months

6.4 Special Precautions for Storage

Do not store above 30^0C. Protect from light. Do not freeze.

6.5 Nature and Contents of Container

A White colour smooth Cream filled in 15 gm aluminimum collapsible tube. Such I tube is packed in a Printed Carton with Packing Insert.

A White colour smooth Cream filled in 20 gm aluminimum collapsible tube. Such I tube is packed in a Printed Carton with Packing Insert.

6.6 Special precaution for disposal and other handling

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

7 Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
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8 Marketing Authorization Number

TAN 21 HM 0438

9 Date of first authorisation/ Renewal of the authorisation
2021-11-26

10 Date of revision of the text