1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: Clotrimazole 0.5% and Ichthammol 0.2%

BRAND NAME: Lulican Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each filled tube contains:
Clotrimazole ……0.5%
Ichthammol……0.2%
Excipients……q.s

For complete list of excipients refer section 6.1.

3. *PHARMACEUTICAL FORM*:

Cream
White to off white cream and very smooth when applied on the skin

4. *CLINICAL PARTICULARS*

4.1 Therapeutic Indication:

a) For the topical treatment of the following dermal infections: Tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes, Epidermophyton floccosum and* Candidiasis due *to Candida albicans* etc
b) For the treatment of skin disorders such as eczema, psoriasis and boils as it is thought to exhibit anti-inflammatory, antibacterial and antimycotic properties.
c) Treating insect bites and stings from mosquitoes, spider, and bees

4.2 Posology and method of administration:

There is no separate dosage schedule for the young or elderly

Method of administration:

The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.
If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warning and precautions for use

Not used for eye, on deep wounds, this product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). Washing clothing and bedding may reduce product build-up but not totally remove it; and it's for external use only.

4.5 Drug Interactions

None known.

4.6 Pregnancy &Lactation

Pregnancy:
There are currently no known harmful side effects associated with the use of clotrimazole and ichthammol cream by pregnant women to either the mother or the unborn child.
Lactation:
Nursing mothers may use clotrimazole and ichthammol cream as needed anywhere except on the breasts where it may be ingested by the nursing infant

4.7 Effects on ability to drive and use machines:

This medicine has no influence on the ability to drive and use machines

4.8 Adverse Effects.

In rare instances, patients may experience an allergic reaction that can include:

- hives
- swelling of the face
- mouth
- throat or hands
- tightness of the chest or difficulty breathing

Skin and subcutaneous tissue disorders: blisters, dermatitis contact, Irritant reactions

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting).

5. *PHARMACOLOGICAL PROPERTIES:*

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal

ATC code: D01AC01

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 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 primarily 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.

Ichthammol has a slight bacteriostatic effect and acts in a similar manner to Coal Tar BP being used in the treatment of the less acute forms of eczema.

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
Ichthammol is applied externally. There is little information available regarding its pharmacokinetics although it is probably not absorbed through intact skin.

5.3 Preclinical Safety Data:

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

6. *PHARMACEUTICAL PARTICULARS*

6.1 List of excipients

- Cetomacrogol 1000 BP
- Cetostearyl Alcohol BP
- Glycerol Monostearate BP
- Benzyl Alcohol
- Liquid Paraffin (Light) BP
- Hard Paraffin BP
- Sodium Methyl Paraben BP
- Sodium Propyl Paraben BP
- Sodium Phosphate BP
- Sodium Acid Phosphate BP

- Propylene Glycol BP
- Fragrance (Lavender) IH

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 months

6.4 Special precautions for storage:

Store in a cool dry place at a temperature not exceeding 25°C.

Protect from light.

6.5 Nature and contents of container

20g cream filled in Collapsible Aluminium tube which is packed in mono carton.

6.6 Special precautions for disposal and other handling

No special requirements.

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

7. *APPLICANT*

SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:
Plot 6, New Makun City,
Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu.
Ogun State,
NIGERIA

Manufactured by:

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NIGERIA

8. *WHO PREQUALIFICATION REFERENCE NUMBER*

Not applicable

9. ***DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION***
Not applicable

10. ***DATE OF REVISION OF THE TEXT***
Not applicable