1. NAME OF THE DRUG PRODUCT

PRODUCT NAME: Clotrimazole Cream 1%

BRAND NAME: Ytacan Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PRODUCT NAME: Clotrimazole Cream 1%

Each grmcontains:
Clotrimazole ……..……..1%
Excipients.....q.s

For complete list of excipients refer section 6.1.

3. PHARMACEUTICALS FORM:

Cream

White creamy and very smooth when applied to the skin

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

i. All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species)
ii. All dermatomycoses due to yeasts (Candida species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrasma and intertrigo.
iii. Skin diseases showing secondary infection with these fungi.
iv. Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and method of administration:

Posology

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.
Treatment should be continued for at least one month for dermatophyte infections, or for at least two weeks for candidal infections.

4.3 Contraindications:

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

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

4.4 Special warning and precautions for use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). The cream also contains benzyl alcohol which may cause allergic reactions and mild local irritation.
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 Drug Interactions

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 & Lactation

Pregnancy:
There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses (see section 5.3). At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy but only under the supervision of a physician or midwife.
Lactation:
There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. Clotrimazole may be used during lactation.
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 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, Website: 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). Gastric lavage should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic 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.

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 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.
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

Cetomacrogol B.P. Cetostearyl Alcohol B.P , Glycerol Monostearate BP , Liquid Paraffin (Light) BP , Hard Paraffin B.P. , Benzyl Alcohol BP , Sodium Methyl Paraben BP , Sodium Propyl Paraben BP , Sodium Phosphate BP , Sodium Acid Phosphate BP , Propylene Glycol BP , Fragrance (Lavender) , Freshly Boiled Purified Water,Freshly Boiled Purified Water q.s.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Store in a cool dry place below 30^0C.

6.5 Nature and contents of container

Aluminium tube with cap.
Pack sizes: 30g

NAFDAC Reg.No : 04-1533

6.6 Special precautions for disposal and other handling

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

7. APPLICANT

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
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