1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

PRODUCT NAME: Clotrimazole 1.0% w/w, Neomycin sulphate 0.5% w/w and Bethamethasone 0.05% w/w

BRAND NAME: Ytacan Plus Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
Clotrimazole ……..……..1.0% w/w
Neomycin sulphate……..0.5% w/w
Bethamethasone……0.05% w/w
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

Route of administration: Cutaneous

Creams are especially appropriate for moist or weeping surfaces.

Ytacan Plus is a combination of three medicines: Betamethasone, Clotrimazole and Neomycin.

Betamethasone is a steroid which blocks the production of certain chemical messengers (prostaglandins) that make the skin red, swollen and itchy. Clotrimazole is an antifungal which stops the growth of fungi while Neomycin is an antibiotic which stops bacterial growth in the skin. Together, they treat your skin infection effectively.

Use this medication on the skin only. Clean and thoroughly dry the area to be treated. Apply a thin layer of the medication to the affected area and gently rub in, usually twice daily (in the morning and evening) or as directed by your doctor. Wash your hands after using unless you are using this medication to treat the hands. Do not wrap, cover, or bandage the area unless directed to do so by your doctor. Wear loose-fitting clothes after applying the medication to the groin area.

Do not apply the medication in the eyes, nose, mouth, or inside the vagina. If you do get the medication in those areas, flush with plenty of water.

The dosage and length of treatment depends on the type of infection being treated. Ringworm or jock itch is usually treated for 2 weeks, and athlete's foot is usually treated for 4 weeks. Do not use more than 45 grams of the cream or 45 milliliters of the lotion per week unless directed and closely monitored by your doctor.

Do not apply more often or use longer than prescribed. This may increase the risk of side effects.

Use this medication regularly to get the most benefit from it. To help you remember, use it at the same times each day.

Continue to use this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

Inform your doctor if your condition worsens or does not improve after 1 week of treatment for jock itch or ringworm or 2 weeks of treatment for athlete's foot

4.3 Contraindications:

Use of Ytacan Plus is considered to be harmful for patients with known allergy to any of the components or excipients of this medicine. Avoid its use in case of any fungal infections (ringworm or athlete's foot), viral infections (herpes or chickenpox) or for treatment of acne or rosacea. Consult your doctor before using it for any condition.

4.4 Special warning and precautions for use

Ytacan Plus should not be used on the face and contact with eyes should be avoided. Do not apply a bandage or dressing on the area being treated, as this will increase absorption of the medicine and increase the risk of side-effects. This medicine should only be used for the condition it is prescribed for. Do not use it for any other condition without consulting your doctor. Do not give it to other people even if their condition appears to be the same.

4.5 Drug Interactions

Antagonism with polyene antibiotics.

4.6 Pregnancy & Lactation

Contraindicated; since Neomycin is contraindicated in pregnancy, the combination generic cannot be used in pregnant woman

4.7 Effects on ability to drive and use machines:

There have been no studies to investigate the effect of Ytacan plus on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical Betamethasone + Clotrimazole + Neomycin

4.8 Undesirable effects

Burning, tingling, dry skin, or stinging may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if any of these unlikely but serious side effects occur: extreme hair growth, skin thinning/discoloration, acne, stretch marks, "hair bumps" (folliculitis).

Rarely, it is possible this medication will be absorbed from the skin into the bloodstream. This can lead to side effects of too much corticosteroid. These side effects are more likely in children, and in people who use this medication for a long time or over large areas of the skin. Tell your doctor right away if any of the following side effects occur: unusual/extreme tiredness, weight loss, headache, swelling ankles/feet, increased thirst/urination, and vision problems.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

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

This medicine may be harmful if swallowed.

5. *PHARMACOLOGICAL PROPERTIES:*

5.1 Pharmacodynamic properties

Cream contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent. Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory anti-pruritic and vasoconstrictive actions. Clotrimazole is a broad-spectrum antifungal agent with activity against Trichomones, Staphylococci and Bacteroides. Neomycin is an aminoglycoside antibiotic that primarily exerts its effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

5.2 Pharmacokinetic properties

Cream intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.

Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

Neomycin is poorly absorbed from the gastrointestinal tract and after topical administration an insufficient amount is absorbed to produce systemic effects. Absorption has been reported to occur from wounds and inflamed skin. After absorption neomycin is rapidly excreted by the kidneys in active form

5.3 Preclinical Safety Data:

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6. *PHARMACEUTICAL PARTICULARS*

6.1 List of excipients

- Benzyl alcohol, Liquid paraffin, hard paraffin,propylene glycol, sodium methyl paraben, sodium acid phosphate, sodium propyl paraben, disodium EDTA, cetromacrogol 1000, cetyl esters wax, cetostearyl alcohol, octyldodecanol, sorbitan monostearate and purified water, fragrance (Emirage Q012)

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Store below 30°C. Do not freeze

6.5 Nature and contents of container

aluminium tube with cap.
Pack sizes: 30g
NAFDAC Reg. No. : A4-2483

6.6 Special precautions for disposal and other handling

Patients should be advised to wash their hands after applying Cream unless it is the hands that are being treated.

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