1.3 Product Information

1.3.1 Summary of product characteristics (SmPC)

Enclosed-

1. NAME OF THE MEDICINAL PRODUCT

CLOTRIMAZOLE 1% W/W + BECLOMETHASONE DIPROPIONATE 0.025% W/W+ NEOMYCIN SULPHATE 0.5% W/W CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP……1% w/w

Beclomethasone Dipropionate USP

Eq. to Beclomethasone ……0.025% w/w

Neomycin Sulphate USP……0.5% w/w

Cream Base……..q.s

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

4. Clinical particulars

4.1 Therapeutic indications

It is a combination of antifungal Clotrimazole, antibacterial Neomycin and anti-inflammatory Beclomethasone.dipropionate.

1. Fungal and bacterial infections of skin

2.Allergic conditions of the skin

4.2 Posology and method of administration

Posology

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

Method of administration

Apply the cream with gentle massage to the affected part 2 - 3 times daily.

4.3 Contraindications

AGB Cream is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids or imidazoles.

If irritation or sensitisation develops with the use of AGB Cream, treatment should be discontinued and appropriate therapy instituted.

AGB Cream is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections

4.4 Special warnings and precautions for use

Local and systemic toxicity is common especially following long continued use on large areas of damaged

skin and in flexures. If used on the face, courses should be limited to 5 days.

AGB cream SHOULD NOT BE USED WITH OCCLUSIVE DRESSING.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.

AGB cream is not intended for ophthalmic use.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population

- Long term continuous therapy should be avoided in all children irrespective of age.
- AGB cream cream should not be used with adhesive dressing.
- The safety and effectiveness of AGB cream has not been established in children below the age of 12.
- If used on children, courses should be limited to 5 days.

Hypothalamic-pituitary adrenal axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

4.5 Interaction with other medicinal products and other forms of interaction

Here are no known interactions.

4.6 Pregnancy and Lactation

Pregnancy

There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence AGB Cream should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Breast-feeding

It is not known whether the components of AGB are excreted in human milk and therefore caution should

be exercised when treating nursing mothers.

4.7 Effects on ability to drive and use machines

Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions include burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses), blurred vision and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

4.9 Overdose

Acute overdosage with topical application of AGB cream is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of AGB cream. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

AGB 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.

5.2 Pharmacokinetic properties

AGB Cream is 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.

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

Name of Ingredients	Reference
Liquid Paraffin	IP
White Petrolium Jelly	IP
Cetosteryl Alcohol	IH
Benzyl Alcohol	IH
PEG 400	IH
Di Sodium Hydrogen Phosphate	IP
Cetomacrogol 1000	IH
D. M. Water	IH

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C.Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

30 Gram Tube

6.6 Special precautions for disposal <and other handling>

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

7. APPLICANT/MANUFACTURER

Applicant:

TYONEX NIGERIA LIMITED

Km 10, LASU-Igando Road,

Igando, Lagos, Nigeria.

Manufacturer:

CENTURION REMEDIES PVT. LTD.

Plot No. G/5, G/6, B.I.D.C.

Gorwa, Vadodara, Gujarat - India