1. NAME OF THE MEDICINAL PRODUCT

CLOTRIMAZOLE, BETAMETHASONE, NEOMYCIN GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole BP 1.0 % w/v, Betamethasone dipropionate USP, Eq. to betamethasone 0.05 % w/w, Neomycin sulfate USP 0.5 % w/w, Eq. to neomycin base 0.35 % w/w

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Topical gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short-term topical treatment of tinea infections due to Trichophyton rubrum; T.mentagrophytes; Epidermophyton floccusum and Microsporum canis; candidiasis due to Candida albicans.

4.2 Posology and method of administration

Posology

Adults and children over the age of 12 years.

Paediatric population

Visita plus gel is not recommended for children under the age of twelve years.

Method of administration

Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidiasis) or for four weeks (tinea pedis).

4.3 Contraindications

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 cream, treatment should be discontinued and appropriate therapy instituted.

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.

Paediatric population

• Long term continuous therapy should be avoided in all children irrespective of age. Visita plus gel should not be used with adhesive dressing.

• The safety and effectiveness of cream has not been established in children below the age of 12.

• If used on children, courses should be limited to 5 days.

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.

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.

Cream is not intended for ophthalmic use.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

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 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 Cream 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

None stated.

4.8 Undesirable effects

Adverse reactions reported for cream 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) 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 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 cream. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics 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.

5.2 Pharmacokinetic properties

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

Cetyl Alcohol, Light Liquid Paraffin, Cremophor RH 40, Isopropyl myristate, Benzyl Alcohol, Polysorbate 60, Glycerol, Sepimax Zen, Glyceryl monostearate, Propylene glycol, Colour Erythrosine Supra, Flavour English Lavender comp P 4154, Titanium dioxide, Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30^0C in a dry place, Protect from light.

6.5 Nature and contents of container

30 gm Aluminium tube packed in a printed carton & leaflet.

6.6 Special precautions for disposal

No special requirements

7. APPLICANT/MANUFACTURER

M/s ELBE PHARMA NIGERIA LIMITED

1, AFRICAN CHURCH CLOSE,

OFF COKER ROAD,

ILUPEJU, LAGOS, NIGERIA

Manufactured by:

S Kant

HEALTHCARE Ltd.
1802-1805, G.I.D.C.,Phase III,

Vapi - 396 195. Gujarat, INDIA.