1. NAME OF THE MEDICINAL PRODUCT

NELB HYDROCORTISONE CREAM

(Hydrocortisone Cream BP 1%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

- Hydrocortisone BP……. (1.00% w/w)
- Cream base …….. (QS)

3. PHARMACEUTICAL FORM

Smooth white cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nelb Hydrocortisone Cream is a mild topical corticosteroid, or 'steroid' used for the relief of mild inflammatory skin disorders including:

- Mild to moderate eczema
- Irritant contact dermatitis or allergic contact dermatitis
- Insect bite reactions

4.2 Posology and method of administration

Route: Topical

Recommended dosage schedules:

Adults: Use sparingly over a small area once or twice daily for a maximum period of one week.

Children: Nelb Hydrocortisone Cream is not recommended for use in children under 12 years without medical supervision.

4.3 Contraindications

Nelb Hydrocortisone Cream is contraindicated for use on the eyes or face, the ano-genital area or on broken or infected skin including cold sores, acne and athletes' foot.

Use in the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.

Use in acne vulgaris, acne rosacea or in perioral dermatoses.

Hypersensitivity to the preparation.

Use in plaque psoriasis.

4.4 Special warnings and precautions for use

Nelb Hydrocortisone Cream is not recommended for use in children under 12 years, except under medical supervision.

Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings may suppress adrenocortical function.

Continuous application without interruption will result in local atrophy of the skin, striae, and superficial vascular dilatation, particularly on the face.

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

Visual disturbance:

Visual disturbance may be reported with systemic and topical 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 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.

The inactive ingredients, cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

4.5 Interaction with other medicinal products

None known.

4.6 Pregnancy and Lactation

Pregnancy Category C

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. The product should not be used in pregnancy unless considered essential by the physician, and then over as small an area and for as short a time as possible.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

Adverse events which have been associated with topical corticosteroids are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Skin and Subcutaneous Tissue Disorders	Very Rare	Local irritation, itching and burning. Striae may occur especially in intertriginous areas.
	Not known	Urticaria Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)
Endocrine Disorders	Not known	Pheochromocytoma crisis
Eye Disorders	Not known	Vision, blurred (see section 4.4)

4.9 Overdose

No special procedures or antidote are likely to be necessary.

Topical overdosage may occur where large amounts are applied, or where smaller amounts are applied in occlusive conditions. Overdose ultimately leads to adrenocortical suppression. Treatment is by gradual reduction of the amounts used. The side effects of overuse i.e. skin atrophy, striae etc. may not be reversed.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic Group: Corticosteroids, dermatological preparations; corticosteroids, weak (group I);

ATC Code: D07AA02

Hydrocortisone, as a mild topical corticosteroid, is used in the treatment of many skin conditions such as eczema, atopic dermatitis, contact dermatitis, seborrhoeic dermatitis and some forms of psoriasis. When administered by topical application, particularly under an occlusive dressing or when the skin is broken, sufficient corticosteroid may be absorbed to give systemic effects.

5.2 Pharmacokinetic properties

The literature states that absorption does occur through the skin, particularly denuded skin. This absorption is not usually of clinical significance as hydrocortisone topically has only rarely been associated with side effects resulting from pituitary-adrenal suppression.

Topically applied steroids may be absorbed to a significant extent if applied to broken skin, to very large areas, or under occlusive dressings.

If systemic absorption occurs, hydrocortisone is extensively bound to plasma proteins, mainly to globulin and less so to albumin. Corticosteroids are metabolized mainly in the liver but also in the kidney, and are excreted in the urine.

5.3 Preclinical safety data

No significant preclinical safety concerns have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- White soft paraffin
- Cetomacrogol emulsifying wax (containing cetostearyl alcohol and macrogol cetostearyl ether)
- Liquid Paraffin
- Chlorocresol
- Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Nelb Hydrocortisone Cream is packaged in internally lacquered aluminium tubes with polyethylene closures containing 15 g of cream.

6.6 Special precautions for disposal and other handling

Not applicable.

7. APPLICANT INFORMATION

M/s. CHRIS NELB PHARMA CO.LTD

ASHGBON STREET, IDUMOTA, LAGOS

LAGOS ISLAND, LAGOS.

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8. MANUFACTURER

M/s. MCCOY PHARMA PVT. LTD.

S-12 & S-13, M.I.D.C., TARAPUR, BOISAR

DIST.: PALGHAR (MH) - 401506