SUMMARY PRODUCT CHARACTERISTICS

1. **Name of the Finished Pharmaceutical Product**

1.1 Proprietary Name
HYCORUM CREAM

1.2 Strength
CONTAINS HYDRORTISONE BP 1% W/W.

1.3 Description
WHITE SEMI-SOLID, NON-GRITTY CREAM.

2. Qualitative and quantitative composition

1.7 Qualitative Declaration

Recommended International Non-proprietary name (INN):

HYDRORTISONE

1.8 Quantitative Declaration
CONTAINS HYDROCORTISONE BP 1.00% w/w

For the full list of excipients see Section 6.1.

3. Pharmaceutical form

Cream.

4. Clinical particulars

4.1 Therapeutic indications
Treatment of mild to moderate inflammatory, allergic and pruritic skin disorders such as eczema, including atopic, infantile discoid and statis eczema, seborrhoeic dermatitis, intertrigo, otitis externa, contact dermatitis, fluxeral psoriasis and lichen simplex.

It is also indicated for relief or irritant contact dermatitis, allergic contact dermatitis, insect bite reactions and mild to moderate eczema.

4.2 Posology and method of administration
Hydrocortisone (Hycorum) cream should be applied sparingly to the affected areas two or three times daily. More frequent application has no beneficial effects and only increase the amount of the corticosteroid absorbed into systemic circulation. In children, it is suggested

that a steroid- free period of 2 weeks be observed after each 2 or 3 weeks of daily topic therapy to allow thinned epidermis to restore itself and maintain its barrier function.

Method of Administration

For topical application.

4.3 Contraindications

Hypersensitivity to hydrocortisone or any of the other ingredients in the product.

Untreated bacterial (e.g. impetigo), viral (e.g. herpes simplex), or fungal (e.g. candida or dermatophyte) infections.

Scabetic infections.

Rosacea.

Perioral dermatitis.

4.4 Special warnings and precautions for use

If the treatment continues longer than two weeks, the risk of systemic side effects will increase especially in children.

In infants and children, long-term continuous topical therapy should be avoided, as adrenal suppression can occur, even without occlusion.

Extreme caution is required in dermatoses of infancy, including napkin rash. In infants, the napkin may act as an occlusive dressing, and increase absorption. Treatment in infants should therefore be limited to five to seven days.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents.

As with all corticosteroids, prolonged application to the face is undesirable.

Keep away from the eyes.

Topical corticosteroids may be hazardous in psoriasis.

This product contains cetostearyl alcohol and chlorocresol amongst the excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorocresol may cause allergic reactions. Treatment with hydrocortisone cream should be discontinued if either of these reactions develops.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions have been reported for topical hydrocortisone.

4.6 Pregnancy and lactation
There is inadequate evidence of safety in human pregnancy. Topical administration of topical 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 the human foetus.

4.7 Effects on ability to drive and use machines
Hydrocortisone does not affect the ability to drive and use machines.

4.8 Undesirable effects
Discontinue treatment should sensitisation occur.

Application to skin folds and moist areas, or in nappy areas in young children, may cause local atrophic changes where constant moist conditions favour the absorption of hydrocortisone. Sufficient systemic absorption may occur which may lead to suppression of the HPA (hypothalamic pituitary adrenal) axis after prolonged treatment. This effect is more likely to occur in infants and children, and if occlusive dressings are used.

Changes in skin pigmentation and hypertrichosis may occur. Contact dermatitis may also occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose
Acute over dosage is very unlikely to occur, however, in the case of chronic overdosage, use under occlusive dressings or misuse the features of hypercorticism may appear and in this situation topical steroids should be discontinued.

There are no special procedures or antidote. Treat any adverse effects symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties
ATC Code: D07 AA02

Pharmacotherapeutic group: Weak dermatological corticosteroid (group 1).

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects, mediated by the reduction of formation, release and action of the various vasoactive chemicals released during inflammation. Thus producing suppression of the clinical manifestations of the disease in a wide range of disorders where inflammation is a prominent feature.

5.2 Pharmacokinetic properties

Absorption

Hydrocortisone is absorbed through skin, particularly in denuded areas.

Distribution

Corticosteroids are rapidly distributed to all body tissues. They cross the placenta to varying degrees and may excreted in small amounts in breast milk. Corticosteroids in the circulation are usually extensively bound to plasma proteins, mainly to globulin and less so to albumin.

Metabolism

Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol.

Excretion

The metabolites are excreted in the urine mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Chlorocresol
Cetomacrogol 1000
Cetostearyl Alcohol
White Soft Paraffin
Liquid Paraffin
Sodium Dihydrogen Phosphate
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years from the date of manufacture.

6.4 Special precautions for storage

Store below 30°C; do not freeze.

6.5 Nature and contents of container

The product containers are collapsible Aluminium tubes with screw caps contained in cartons: **Pack sizes:** 15g.

6.6 Special precautions for disposal and other handling
Not applicable.

7. Registrant:

Company name: LABORATORY & ALLIED LTD
Address: PLOT NO.209/ 10349, OPP. SAMEER AFRICA, NEXT TO LIBRA HOUSE,
MOMBASA ROAD. P. O. BOX 42875, GPO 00100, NAIROBI.
Country: KENYA
Telephone: + 254 – 20-8040306
Telefax: 254 – 020 - 8040309
E-Mail: info@laballied.com

Manufacturing site

Company name: LABORATORY & ALLIED LTD
Address: PLOT NO.209/ 10349, OPP. SAMEER AFRICA, NEXT TO LIBRA HOUSE,
MOMBASA ROAD. P. O. BOX 42875, GPO 00100, NAIROBI.
Country: KENYA
Telephone: + 254 – 20-8040306
Telefax: 254 – 020 - 8040309
E-Mail: info@laballied.com

8. Marketing Authorization Number:
UGANDA: NDA/MAL/HDP/4927
KENYA: H95/095
TANZANIA: TAN 00, 1861 D07A LAA
MALAWI: PMPB/PL108/24
ZAMBIA: 309/002
BOTSWANA: BOT 1602866

9. Date of first Registration/ Renewal of the Registration:
KENYA: 1995

10. Date of revision of the text:
July 2017