1. Name of the medicinal product

Lucin cream

2. Qualitative and quantitative composition

Each 1 gram of the cream contains 1%w/w of hydrocortisone.

Excipients with known effect

Contains 1 mg of chlorocresol and emulsifying wax.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Cream for cutaneous use only.

A white opaque almost odourless cream, free from visible impurities.

4. Clinical particulars

4.1 Therapeutic indications

Hydrocortisone has topical anti-inflammatory activity of value in the treatment of a wide variety of dermatological conditions, including the following: eczema and dermatitis of all types including atopic eczema, photodermatitis, intertrigo, primary irritant and allergic dermatitis, prurigo nodularis, seborrheic dermatitis and insect bite reactions.

4.2 Posology and method of administration

Posology

Use sparingly over a small area once/twice a day for a maximum period of one week. If the condition has not improved, or worsens, consult your doctor.

This product should not be recommended for use on children under 10 years of age without medical advice.

Method of administration.

For cutaneous use

4.3 Contraindications

Bacterial (e.g., impetigo), viral (e.g., Herpes simplex) or fungal (e.g., candida or dermatophyte) infections of the skin.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Use on the face, Ano-genital region, Broken or infected skin including cold sores, acne and athlete's foot.

4.4 Special warnings and precautions for use

Remarks on indications

1. There is no good evidence that topical corticosteroids are efficacious against immediate (Type 1) allergic skin reactions or short-lived weal and flare reactions from other causes.
2. Topical corticosteroids are ineffective in granulomatous conditions and other inflammatory reactions involving the deeper regions of the dermis.
3. Topical corticosteroids are not generally indicated in psoriasis excluding widespread plaque psoriasis provided that warnings are given.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalized pustular psoriasis, and local and systematic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Although generally regarded as safe, even for long-term administration in adults, there is potential for overdosage in infants and children. Extreme caution is required in dermatoses of infancy especially napkin eruption where the napkin can act as an occlusive dressing and increase absorption. In infants and children, courses of treatment should therefore not normally exceed 7 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 a systemic administration of antimicrobial agents.

As with all corticosteroids, prolonged application to the face is undesirable. Do not use under an occlusive dressing.

This medicinal product contains chlorocresol, which may cause allergic reactions.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.

4.5 Interaction with other medicinal products and other forms of interaction

There is no known interaction.

4.6 Fertility, pregnancy, and lactation

Pregnancy

There is inadequate evidence of safety in human pregnancy. 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 the human foetus.

Breastfeeding

There is no evidence against use in lactating women. However, caution should be exercised when Hydrocortisone Cream is administered to nursing mothers. In this event, the product should not be applied to the chest area.

4.7 Effects on ability to drive and use machines

There is no known effect on driving and machine use.

4.8 Undesirable effects

Hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity appear, application should stop immediately.

Striae may occur especially in intertriginous areas.

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, weak (group I); ATC code: D07A A02

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of Hydrocortisone on connective tissue. Stabilisation of most cell granules and lysomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes in prostaglandin synthesis. The vasoconstrictor action of Hydrocortisone may also contribute to its anti-inflammatory activity.

5.2 Pharmacokinetic properties

Absorption: Topically applied steroids are absorbed to a significant extent only if applied to broken skin, to very large areas, or under occlusive dressings.

Distribution: Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk.

Metabolism: Hydrocortisone is metabolised mainly in the liver, but also the kidney, to various degraded and hydrogenated forms such as tetrahydrocortisone.

Elimination: Hydrocortisone is excreted in the urine, mostly conjugated as glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data

Adverse effects of Hydrocortisone are due to its effects on electrolyte balance, metabolism and particularly adrenal suppression. Topical use of Hydrocortisone has only rarely been associated with systemic side effects.

6. Pharmaceutical particulars

6.1 List of excipients

Emulsifying wax

Petroleum Jelly (Snow White Merkur 500)

Liquid Paraffin

Glycerine

Triethanolamine

Stearic Acid

Chlorocresol

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C, in a dry place. Protect from light. Keep out of reach of children

6.5 Nature and composition of containers

Pack Size: 15gms Aluminium tubes 15gms

6.6 Instruction for use/handling

Read package insert before use.

6.7 Restriction on sale / distribution:

Pharmacy Only Sale

7.Registrant

Name and address of holder of a registration. Regal Pharmaceuticals Limited

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Date of first registration- 01//09/2009

8. Manufacturer

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9. Marketing Authorisation Number(S)

3959-987

10. Date Of First Authorisation/Renewal of The Authorisation

08/05/07

11. Date of Revision of The Text

26th January, 2026.