Hydrocortisone
Lacticare-HC
Lotion

PRODUCT DESCRIPTION
Hydrocortisone (Lacticare-HC) 1% Lotion contains 1% w/v Hydrocortisone.
Hydrocortisone (Lacticare-HC) 2.5% Lotion contains 2.5% w/v Hydrocortisone.

CLINICAL PHARMACOLOGY

Mechanism of action
Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Pharmacodynamics
Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

Pharmacokinetics
Absorption
Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution
The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism
Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolized, primarily in the liver.

Elimination
Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

NON-CLINICAL INFORMATION

Carcinogenesis
Hydrocortisone was not carcinogenic in rats when administered via the subcutaneous route for 52 weeks.

Genotoxicity
Hydrocortisone was not mutagenic in a bacterial mutagenicity assay (Salmonella typhimurium) in the absence or presence of metabolic activation, and was not genotoxic in an unscheduled DNA synthesis (UDS) assay in rat primary hepatocytes. Hydrocortisone was genotoxic in a chromosome aberration assay in human lymphocytes, and a mouse bone marrow micronucleus/sister chromatid exchange assay.

Fertility
The effect on fertility of hydrocortisone has not been evaluated in animals.

Pregnancy
Subcutaneous administration of hydrocortisone to mice at doses \( \geq 30 \) mg/kg/day and rabbits at a dose of 675 µg/kg/day and a single intramuscular injection of \( \geq 25 \) mg to hamsters during pregnancy produced foetal abnormalities including cleft palate.

INDICATIONS

Hydrocortisone (Lacticare-HC) Lotion is a mild topical corticosteroid indicated for adults, elderly, children and infants for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. These include the following:

- Atopic dermatitis (including infantile atopic dermatitis)
- Nummular dermatitis (discoid eczemas)
- Prurigo nodularis.
- Lichenifications (neurodermatoses) including lichen simplex chronicus.
- Seborrhoeic dermatitis.
- Irritant or allergic contact dermatitis.
- Discoid lupus erythematosus.
- An adjunct to systemic steroid therapy in generalised erythroderma.
- Insect bite reactions.
- Miliaria (prickly heat).
- Otitis externa.

DOSAGE AND ADMINISTRATION

Adults, elderly, children and infants

Lotions are especially appropriate for treatment of hairy areas or when a minimal application to a large area is required. Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day until improvement occurs, then reduce the frequency of application. Allow adequate time for absorption after each application before applying an emollient. If the condition worsens or does not improve within 4 weeks, treatment and diagnosis should be re-evaluated.

Therapy with Hydrocortisone (Lacticare-HC) should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy. Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroids.
Children
Children are more likely to develop local and systemic side effects of topical corticosteroids and in general, require shorter courses than adults.
Care should be taken when using Hydrocortisone (Lacticare-HC) to ensure the amount applied is the minimum that provides therapeutic benefit.

Elderly
Clinical studies have not identified differences in responses between the elderly and younger patients. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

Renal / Hepatic Impairment
In case of systemic absorption (when application is over a large surface area for a prolonged period) metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration to achieve the desired clinical benefit.

CONTRAINDICATIONS
The following conditions should not be treated with Hydrocortisone (Lacticare-HC):
- Untreated cutaneous infections
- Rosacea
- Acne vulgaris
- Pruritus without inflammation

WARNINGS AND PRECAUTIONS
Hydrocortisone (Lacticare-HC) should be used with caution in patients with a history of local hypersensitivity to corticosteroids or to any of the excipients in the preparation. Local hypersensitivity reactions (see Adverse Reactions) may resemble symptoms of the condition under treatment. Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see Adverse Reactions).
Risk factors for increased systemic effects are:
- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin (e.g. on intertriginous areas or under occlusive dressings (in infants the nappy may act as an occlusive dressing)
- Increasing hydration of the stratum corneum
- Use on thin skin areas such as the face
- Use on broken skin or other conditions where the skin barrier may be impaired
- In comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to body weight ratio compared with adults.

Children
In infants and children under 12 years of age, long-term continuous topical therapy should be avoided where possible, as adrenal suppression is more likely to occur.

Infection risk with occlusion
Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings the skin should be cleansed before a fresh dressing is applied.

Application to the face
Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes.

Application to the eyelids
If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataracts and glaucoma might result from repeated exposure.

Concomitant infection
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 administration of appropriate antimicrobial therapy.

Chronic leg ulcers
Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Effects on Ability to Drive and Use Machines
There have been no studies to investigate the effect of Hydrocortisone (Lacticare-HC) on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical hydrocortisone.

DRUG INTERACTIONS
Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

PREGNANCY AND LACTATION
Fertility
There are no data in humans to evaluate the effect of topical hydrocortisone on fertility.
Pregnancy
Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development (see Non-clinical Information). The relevance of this finding to human beings has not been established; however, administration of Hydrocortisone (Lacticare-HC) during pregnancy should only be considered if the expected benefit to the mother outweighs the risk to the foetus. The minimum quantity should be used for the minimum duration.

Lactation
The safe use of topical corticosteroids during lactation has not been established. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Administration of Hydrocortisone (Lacticare-HC) during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant. If used during lactation Hydrocortisone (Lacticare-HC) should not be applied to the breasts to avoid accidental ingestion by the infant.

ADVERSE EFFECTS
Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000) and very rare (<1/10,000), including isolated reports.

Post-marketing data

Immune system disorders

Very rare: Local hypersensitivity

Endocrine disorders

Very rare: Hypothalamic-pituitary adrenal (HPA) axis suppression:
 Increased weight / obesity, delayed weight gain/growth retardation in children, cushingoid features (e.g. moon face, central obesity), decreased endogenous cortisol levels, hyperglycaemia/glucosuria, hypertension, osteoporosis, cataract, glaucoma, steroid withdrawal syndrome

Skin and subcutaneous tissue disorders

Very rare: contact dermatitis /dermatitis, erythema, rash, urticaria, pruritus, skin pain, skin atrophy, dry skin / skin exfoliation, skin striae, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms

General Disorders and Administration Site Conditions

Very rare: Application site irritation/pain

OVERDOSAGE AND TREATMENT
Symptoms and signs
Topically applied hydrocortisone may be absorbed in sufficient amounts to produce systemic effects. Acute overdose is very unlikely to occur, however, in the case of chronic overdose or misuse the features of hypercortisolism may occur (see Adverse Reactions).

Treatment
In the event of overdose, Hydrocortisone 9Lacticare-HC) should be withdrawn gradually by reducing the frequency of application because of the risk of glucocorticosteroid insufficiency. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

STORAGE CONDITION
Store at temperatures between 15°C - 30°C.

AVAILABILITY
25mL Plastic bottle. Box of 1’s

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription. Keep all medicines out of reach of children.

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