

LEMNIS® FATTY CREAM HC

Hydrocortisone 1%

Presentation

Cream: white or nearly white, containing 1% hydrocortisone. The inactive ingredients of LEMNIS FATTY CREAM HC are white soft paraffin, liquid paraffin, cetostearyl alcohol, Macrogol (25) cetostearyl ether, citric acid, sodium citrate, methyl parahydroxybenzoate and purified water.

Uses

Actions

LEMNIS FATTY CREAM HC contains hydrocortisone, a non-halogenated corticosteroid for topical application with anti-inflammatory and antipruritic activity. It has fewer side-effects on the skin and is less liable to induce adrenal suppression than the more potent halogenated topical corticosteroids. The specially formulated base makes it suitable for application to all varieties of responsive dermatological conditions where otherwise a choice should have been made between a traditional cream and an ointment presentation.

LEMNIS FATTY CREAM HC can be washed off and is therefore cosmetically acceptable.

Pharmacokinetics

Hydrocortisone is absorbed through the skin, particularly in areas where the epidermis is damaged; occlusive dressings enhance absorption approximately ten-fold or greater.

Hydrocortisone is metabolized in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

Indications

Skin conditions, responsive to topical corticosteroids, e.g. eczema and dermatitis. It can also be used as supportive therapy in conditions that have previously been treated with more potent corticosteroids. The product is intended for topical administration.

Dosage and Administration

Apply 1-2 times daily a small amount of LEMNIS FATTY CREAM HC onto the affected skin, or as directed by physician. After improvement, application once daily or two to three times a week is usually adequate.

Contraindications

- Skin lesions caused by:
 - tuberculous and syphilitic infections
 - viral infections (e.g. varicellae, herpes simplex, herpes zoster, verrucae vulgares, verrucae planae, condylomata, mollusca contagiosa)
 - mycotic infections
 - parasitic infections (such as scabies)
- Ulcerated skin lesions, wounds
- Adverse reactions induced by corticosteroids (e.g. dermatitis perioralis, striae atrophicae)
- Fragility of the skin vessels, skin atrophy
- Allergic hypersensitivity to components of the vehicle or to corticosteroids (the latter rarely occurs)

Warnings and Precautions

- In case of hypersensitivity to any of the ingredients of the preparation treatment should be stopped.
- Co-existing infection may require specific anti-infective treatment or withdrawal of therapy.
- In children the application of topical steroids should be as short as possible. Babies and children up to four years should not be treated longer than 3 weeks. In infants the napkin may act as an occlusive dressing and increase absorption.
- Applications to extensive skin areas, and prolonged treatment, should be avoided (see **Adverse Effects**).
- During prolonged treatment or when applied to extensive or sensitive skin areas (see below) adrenal suppression may occur, particularly in infants and children.

- Application to sensitive skin areas such as the flexural, facial, genital skin or skin folds should be well monitored and kept as short as possible.
- Contact with the eye should be avoided because there is a potential risk of glaucoma and cataract.

Pregnancy and Lactation

Corticosteroids are known to pass the placenta and may therefore influence the foetus. This will be mainly of significance, however, in case of an intensive treatment of large surfaces with a potent or very potent product. In animal tests corticosteroids were demonstrated to be teratogenic. It is not known whether corticosteroids absorbed through the skin may be demonstrated in mother's milk. If large amounts of LEMNIS FATTY CREAM HC are applied one should be careful with breast-feeding.

Effects on Ability to Drive and Use Machines

There are no data available on the effect of LEMNIS FATTY CREAM HC on the ability to drive and use machines, but no effects of LEMNIS FATTY CREAM HC are to be expected.

Adverse Effects

Local effects

- Skin atrophy, often irreversible, with thinning of the epidermis, telangiectasias, purpura and striae
- Rosacea-like and perioral dermatitis with or without skin atrophy
- "Rebound effect", which may lead to dependence on steroids
- Effects on the eye: increased intraocular pressure, increased chance of a cataract
- Depigmentation, hypertrichosis
- Contact allergy

The incidence of local adverse reactions increases with the strength of the product (e.g. halogenation) and the duration of treatment. Application under occlusion (plastic, skin folds) increases this risk. If used incorrectly, bacterial, parasitic, fungal and viral infections may be masked and/or aggravated.

Systemic effects

Systemic effects as a consequence of topical application of corticosteroids in adults rarely occur. Inhibition of the adrenal cortex may especially be of importance in long-term treatment with more potent corticosteroids.

The risk of systemic effects is highest in:

- Application under occlusion (plastic, skin folds)
- Application on large surfaces
- Long-term treatment
- Application in children (the thin skin and the relatively large surface of the skin make children very sensitive)
- Presence of components or excipients which increase the penetration through the stratum corneum and/or the effect (e.g. salicylic acid, urea, propylene glycol, coal tar).

Interactions

None stated.

Overdosage

There are no data available on an overdose of LEMNIS FATTY CREAM HC. In the case of chronic overdose, symptoms of hypercorticism might occur.

Pharmaceutical Precautions

Shelf-life

LEMNIS FATTY CREAM HC can be kept until the date mentioned on the pack. The shelf-life is 3 years.

Special Precautions for Storage

LEMNIS FATTY CREAM HC can be kept at room temperature (15-25°C).

Medicine Classification

100g Prescription Medicine.

Package Quantities

Tubes of 100g.

Further Information

The base of LEMNIS FATTY CREAM HC is a unique cream emulsion with a high concentration of fatty substances suspended in water as the continuous phase. It has the cooling and vanishing properties of a cream and the occlusive properties of an ointment with its protective and emollient effects.

LEMNIS FATTY CREAM HC is therefore well suited for the treatment of subacute and chronic skin conditions.

Name and Address

CSL Biotherapies (NZ) Ltd
666 Great South Rd
Central Park
Auckland
New Zealand

Ph: 0800 502 757

Date Of Preparation

27 March 2008

LEMNIS® is a registered trademark of Astellas Pharma Europe B.V.