

## **LOCOID-C CREAM™**

0.1% hydrocortisone-17-butyrate and 3% chlorquinaldol

### **Presentation**

LOCOID-C CREAM, containing 0.1% hydrocortisone butyrate and 3% chlorquinaldol, in a cream base. The inactive constituents in LOCOID-C CREAM are cetostearyl alcohol, cetomacrogol, liquid paraffin, white soft paraffin, sodium citrate, citric acid, and purified water.

### **Uses**

#### **Actions**

LOCOID-C CREAM contains hydrocortisone-17-butyrate, a non-halogenated corticosteroid for topical application with anti-inflammatory and anti-pruritic activity. It has fewer side-effects on the skin and is less liable to induce adrenal suppression than the more potent halogenated topical corticosteroids.

LOCOID-C CREAM also contains the antiseptic chlorquinaldol which is not only active against gram-positive bacteria, but also against yeasts (e.g. candida species) and fungi (e.g. species of the genera Trichophyton, Epidermophyton and Microsporum).

#### **Pharmacokinetics**

Hydrocortisone is absorbed through the skin, particularly in denuded areas; 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**

The product is recommended for clinical use in the treatment of conditions responsive to topical corticosteroids, e.g. eczema, dermatitis and psoriasis, where secondary bacterial or fungal infection by a micro-organism susceptible to chlorquinaldol is present or is to be prevented.

The product is intended for topical application.

### **Dosage And Administration**

#### **Adults, Children and the Elderly**

To be applied to the affected part two to four times a day, or as directed by the physician.

### **Contraindications**

- Skin lesions caused by:
  - bacterial infections (e.g. pyodermias, luetic and tuberculous processes)
  - viral infections (e.g. varicellae, herpes simplex, herpes zoster, verrucae vulgares, verrucae planae, condylomata, mollusca contagiosa)
  - mycotic and yeast infections
  - parasitic infections (e.g. scabies)
- Ulcerous skin lesions, wounds
- Adverse reactions induced by corticosteroids (e.g. dermatitis perioralis, striae atrophicae)
- Ichthyosis, juvenile dermatosis plantaris, acne vulgaris, acne rosacea, fragility of the skin vessels, skin atrophy
- Allergic hypersensitivity to components of the vehicle or to corticosteroids (the latter rarely occurs)

### **Warnings And Precautions**

- Occlusive dressings are not recommended in the presence of infections.
- When steroids, and particularly halogenated steroids, are applied to large areas of the body (about 10% and more) and/or for long periods of time (more than four weeks) the occurrence of atrophic striae is likely especially if an occlusive dressing is used.
- Prolonged use on the flexures is undesirable. Adrenal suppression can occur, even without occlusion.
- With daily use of 15g or more over long periods, especially under occlusion, systemic absorption may occur. At such a time routine steroid precautions must be observed if the patient is stressed, e.g. as in surgery. Adrenal suppression is more likely to occur in infants and children.
- In children the application of topical steroids should be limited as much as possible. Inhibition of the adrenal function may occur rather rapidly. In addition, inhibition of growth hormone excretion may occur. If long-term treatment is necessary, it is therefore advisable to check length and weight as well as the plasma cortisol level regularly. 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.

- The skin of the face, pilous skin and the skin of the genitals are particularly sensitive to corticosteroids; it is therefore desirable to treat these areas primarily only with weak corticosteroids.
- Do not apply on the eyelids because of the possibility of contamination of the conjunctiva with the risk of inducing glaucoma simplex or a subcapsular cataract.
- In case of hypersensitivity to any of the ingredients of the preparation treatment should be stopped.

### **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 LOCOID-C CREAM are applied, one should be careful with breast-feeding.

### **Effects on Ability to Drive and Use Machinery**

There are no data available on the effect of LOCOID-C on the ability to drive and use machines, but no effects 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 and the duration of treatment. Application under occlusion (plastic, skin folds) increases this risk.

The skin of the face, pilous skin and the skin of the genitals are especially sensitive to local effects. 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, but may be serious.

Inhibition of the adrenal cortex may especially be of importance in long-term treatment.

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 LOCOID-C. In the case of chronic overdose, symptoms of hypercorticism might occur.

### **Pharmaceutical Precautions**

#### **Shelf-Life**

LOCOID-C CREAM can be kept until the date mentioned on the pack. The shelf-life is 3 years.

#### **Special Precautions for Storage**

LOCOID-C cream can be kept at room temperature (15-25°C).

**Medicine Classifications**

Prescription Medicine.

**Package Quantities**

Tubes of 15g as an original pack.

**Further Information**

Locoid is a non-fluorinated topical steroid. Whilst clinical trials have shown it to be as effective as the potent fluorinated steroids, in clinical practice there is a low incidence of reported side-effects. Chlorquinaldol is an effective topical antibacterial and antimycotic.

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