

# LOCOID®

hydrocortisone 17-butyrate 0.1%

## **Presentation**

Cream: white, containing 0.1% hydrocortisone 17-butyrate.

Lipocream: white or nearly white, containing 0.1% hydrocortisone 17-butyrate.

Ointment: white, containing 0.1% hydrocortisone-17-butyrate.

Topical Emulsion (LOCOID Crelo®): a practically white emulsion containing 0.1% hydrocortisone 17-butyrate.

Scalp Lotion: clear, colourless solution, containing 0.1% hydrocortisone 17-butyrate.

## **Uses**

### **Actions**

The active component of LOCOID preparations is the synthetic corticosteroid hydrocortisone 17-butyrate, which on account of its anti-inflammatory, anti-eczematous, anti-allergic and anti-pruritic properties is indicated in the topical treatment of a great variety of acute and chronic skin disorders. Therapeutically effective concentrations of the corticosteroid are obtained in the skin tissues by percutaneous absorption or penetration resulting in a rapid anti-inflammatory and anti-pruritic effect. LOCOID is therefore eminently suitable for the treatment of eczemas and dermatitis characterized by primary or secondary efflorescences which have been found to respond to corticosteroid treatment, e.g. psoriasis, lichen simplex.

To support the effect of LOCOID, several presentations are available for the treatment of various skin disorders. For the treatment of chronic skin disorders with formation of scales, dry skin lesions and skin lesions with fissures and seborrhoea LOCOID ointment will be preferred. LOCOID lipocream is suitable for the treatment of subacute and chronic skin lesions, particularly in patients with a dry skin. For the treatment of acute and subacute disorders of the hairy parts of the skin and disorders localized in the intertriginous areas LOCOID Crelo topical emulsion and LOCOID Scalp Lotion are indicated. In acute, very moist skin disorders it may be necessary to use LOCOID cream.

### **Pharmacokinetics**

Once absorbed through the skin hydrocortisone 17-butyrate is metabolised primarily by the liver to hydrocortisone and other metabolites. The metabolites and traces of intact hydrocortisone 17-butyrate are excreted with the urine or into the bile.

### **Indications**

Corticosteroid for topical application. The products are recommended for clinical use in the treatment of conditions responsive to topical corticosteroids, e.g. eczema, dermatitis and psoriasis.

### **Dosage And Administration**

For adults and children, to be applied to the affected parts one to four times a day, or as directed by the physician.

In a controlled trial, once daily administration was associated with a slower rate of skin clearance and may, therefore, be especially recommended in cases where considerations of convenience and/or compliance arise.

Where necessary, application may be made under an occlusive dressing.

### **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**

- In pregnant animals, administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for long periods.
- LOCOID Crelo contains parabens, which might have a sensitizing effect. In case of hypersensitivity to any of the ingredients of the preparation treatment should be stopped.
- Co-existing infection may require specific chemotherapy or withdrawal of therapy.
- When steroids, and particularly fluorinated 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.

### **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.

### **Effects On Ability To Drive And Use Machines**

There are no data available on the effect of hydrocortisone-17-butyrate 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
- delay of the wound healing process
- 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.

Hypersensitivity has been reported in the literature, although the incidence is unknown.

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 (propylene glycol)

### **Interactions**

No data are available.

### **Overdosage**

There are no data available on an overdose of LOCOID. In case of chronic overdose symptoms of hypercorticism might occur.

### **Pharmaceutical Precautions**

#### **Shelf-Life**

Lipocream: 36 months  
Cream: 48 months  
Ointment: 60 months  
Scalp Lotion: 24 months  
Crelo: 24 months

Store below 25°C.

### **Medicine Classification**

Prescription Medicine.

### **Package Quantities**

LOCOID cream, ointment: tubes of 15g, 30g and 100g.

LOCOID lipocream: tubes of 30g, 100g.

LOCOID Crelo topical emulsion: polyethylene containers of 30ml, 50ml or 100ml

LOCOID scalp lotion: bottles of 100ml and 250ml.

### **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 clinical side-effects.

### **Name And Address**

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### **Date Of Preparation**

6 March 2008

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