

## NEW ZEALAND DATA SHEET

### 1 LOCOID®

Lipocream  
Ointment  
Topical Emulsion (Locoid Crelo®)  
Scalp Lotion

hydrocortisone butyrate

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each formulation contains active ingredient 0.1% hydrocortisone butyrate.  
For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

**Lipocream:** white or nearly white cream  
**Ointment:** white ointment  
**Topical Emulsion (Locoid Crelo®):** a practically white emulsion  
**Scalp Lotion:** clear, colourless solution

### 4 CLINICAL PARTICULARS

#### 4.1 Indications

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

#### 4.2 Dosage and method of 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.

#### 4.3 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).

#### **4.4 Special warnings and precautions for use**

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.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

With daily use of 15 g 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.

#### **4.5 Interaction with other medicines and other forms of interaction**

No data are available.

#### **4.6 Fertility, 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.

#### **4.7 Effects on ability to drive and use machines**

There are no data available on the effect of hydrocortisone butyrate on the ability to drive and use machines, but no effects are to be expected.

#### **4.8 Undesirable 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)

##### **Further information**

Locoid<sup>®</sup> 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.

##### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

#### **4.9 Overdose**

There are no data available on an overdose of Locoid<sup>®</sup>. In case of chronic overdose symptoms of hypercorticism might occur.

Contact the Poisons Information Centre on 0800 POISON or 0800 764 766 for further advice on overdose management.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

The active component of Locoid<sup>®</sup> preparations is the synthetic corticosteroid hydrocortisone 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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup> ointment will be preferred. Locoid<sup>®</sup> 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<sup>®</sup> topical emulsion and Locoid<sup>®</sup> Scalp Lotion are indicated.

### 5.2 Pharmacokinetic properties

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

### 5.3 Preclinical safety data

No specific data are available.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

**Lipocream:** benzyl alcohol, cetomacrogol 1000, cetostearyl alcohol, citric acid, light liquid paraffin, propyl hydroxybenzoate, purified water, sodium citrate, white soft paraffin

**Ointment:** Liquid paraffin, polyethylene oleogel

**Topical Emulsion (Locoid Crelo<sup>®</sup>):** borage oil, butyl hydroxybenzoate, butylated hydroxytoluene, cetomacrogol, cetostearyl alcohol, citric acid, hard paraffin, propyl hydroxybenzoate, propylene glycol, purified water, sodium citrate dehydrate, white soft paraffin

**Scalp Lotion:** citric acid, glycerol, isopropyl alcohol, povidone, purified water, sodium citrate.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf-life

Lipocream:	36 months
Ointment:	60 months
Topical Emulsion (Locoid Crelo <sup>®</sup> ):	24 months
Scalp Lotion:	24 months

### 6.3 Special precautions for storage

Store below 25°C.

#### **6.4 Nature and contents of container**

Locoid<sup>®</sup> Lipocream: aluminium tubes of 30 g or 100 g.  
Locoid<sup>®</sup> ointment: aluminium tubes of 100 g.  
Locoid Crelo<sup>®</sup> topical emulsion: polyethylene containers of 100 g  
Locoid<sup>®</sup> Scalp Lotion: plastic bottle of 100 ml

### **7 MEDICINE SCHEDULE**

Prescription Medicine.

### **8 SPONSOR**

Link Pharmaceuticals Ltd.  
Suite 32, Level 26  
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New Zealand  
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### **9 DATE OF FIRST APPROVAL**

Locoid<sup>®</sup> Lipocream: 19 October 1983  
Locoid<sup>®</sup> ointment: 10 October 1974  
Locoid Crelo<sup>®</sup> topical emulsion: 24 August 1993  
Locoid<sup>®</sup> Scalp Lotion: 10 April 1974

### **10 DATE OF REVISION OF TEXT**

04 November 2021

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#### **Summary Table of Changes**

<b>Section changed</b>	<b>Summary of new information</b>
Section 8	Updated Sponsor details