PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

Locoid Crelo®, 1 mg/ 1 g, topical emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 17-butyrate 1 mg per 1 g in a buffered oil in water emulsion.

Preservatives:

Propyl parahydroxybenzoate 0,3 % m/m.

Butyl parahyroxybenzoate 0,15 % m/m.

Anti-oxidant:

Butylhydroxytoluene 0,02 % m/m.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical emulsion.

A practically white emulsion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of superficial corticosteroid responsive dermatoses which are not caused by microorganisms and which are expected to respond inadequately to less potent corticosteroids.

4.2 Posology and method of administration

Long term topical use of corticosteroids should be avoided especially in children. A small amount of LOCOID CRELO® should be applied onto the skin, 1-3 times daily. After improvement of the disorder, application once daily or two to three times a week is usually adequate.

Locoid Crelo® is suitable for the treatment of weeping skin disorders on visible places and disorders of the hairy skin.

Locoid Crelo® may be washed off.

Method of administration

For cutaneous use.

Locoid Crelo® should be applied evenly in a thin layer onto the diseased skin.

To promote penetration it may be lightly massaged into the skin.

Sometimes it may be advisable to cover weeping disorders afterwards with a occlusive dressing.

4.3 Contraindications

- Hypersensitivity to the hydrocortisone butyrate or to any of the excipients listed in section 6.1.
- Skin lesions caused by:
- Viral infections (e.g. varicella, herpes simplex, vaccinia herpes zoster, verrucae vulgaris, verrucae planae, condylomata, mollusca contagiosa)
- Bacterial infections (e.g. pyodermas, luetic and tuberculous processes)
- Mycotic and yeast infections
- Parasitic infections (e.g. scabies)
- Ulcerous skin lesions, wounds and broken skin
- Adverse reactions induced by corticosteroids (e.g., dermatitis perioralis, striae atrophicae)
- Icthyosis, juvenile dermatosis plantaris, acne vulgaris, acne rosacea, fragility of the skin vessels or skin atrophy

- The use of this product is not recommended in children under 2 years.
- Corticosteroids have been shown to be teratogenic in animals following dermal application. As these medicines are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore Locoid Crelo® should not be used during pregnancy. The use of Locoid Crelo® is not recommended during lactation.

4.4 Special warnings and precautions for use

For external use only.

Do not apply to broken skin.

Avoid contact near the eyes.

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.

Topical application of corticosteroid preparations to the eyes has produced corneal ulcers, raised intra-ocular pressure, and reduced visual function.

Application to the face, genitals, flexures and other areas of thin skin may cause loss of collagen and skin atrophy and increased absorption and should be avoided. Hands must be washed after each application unless Locoid® is used to treat the hands.

There is an increased risk of systemic and local adverse reactions in treatment of intertriginous areas, large areas of skin or, under occlusion, as well as with frequent dosing or treatment over a long period of time. Attention must be paid to the risks of systemic adverse reactions including adrenocortical suppression.

Due to the immunosuppressant and anti-inflammatory effect of corticosteroids, Locoid Crelo® may be associated with increased susceptibility to skin infections, aggravation of existing infection, and activation of latent infection. As such, Locoid Crelo® is contraindicated against use on infected skin (see section 4.3) and should be used with particular caution at the site of previous or suspected infections.

If a secondary microbial skin infection is present, suitable concomitant anti-microbial therapy should be instituted. Topical corticosteroids should be used with particular caution in facial dermatoses and only for short periods.

In some patients with psoriasis, topical corticosteroids may cause rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin. Steroids may have a place in psoriasis of the scalp and chronic plaque psoriasis of the hands and feet.

Careful patient supervision is important.

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment, a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

Potent topical corticosteroids should be used for short courses only. Do not use indiscriminately for pruritus. Regular review should be made of the necessity for continuing therapy.

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.

Do not apply to any skin crease areas.

Locoid Crelo® contains butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis) and irritation to the eyes and mucous membranes (e.g. nose). The propylene glycol may cause skin irritation. Locoid Crelo® contains propyl parahydroxybenzoate and butyl parahydroxybenzoate which may cause allergic reactions that can be delayed.

Instruct patients not to smoke or go near naked flames due to a risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Paediatric population

The use of this product is not recommended in children under 2 years (see section 4.3).

These corticosteroid preparations should not be used in the nappy areas of infants for flexural eruptions and ideally should not be used on infants and young children at all.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Pregnancy

Locoid Crelo® should not be used during pregnancy.

Breastfeeding

The use of Locoid Crelo® is not recommended during lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA System Organ Class	**Less frequent**	**Frequency unknown**
Immune system disorders		Hypersensitivity
Endocrine disorders	Adrenal suppression	
Eye disorders		Blurred vision*
Skin and subcutaneous tissue disorders	Skin atrophy** Dermatitis*** Telangiectasia Ecchymosis Loss of elasticity Skin striae Purpura Acne Perioral dermatitis Skin depigmentation	Pruritis Erythema Rash Withdrawal reactions

	Hypertrichosis Rosacea-like dermatitis with or without skin atrophy Delay of the wound healing process	
General disorders and administration site conditions	Rebound effect	Application site pain

*See also section 4.4

**often irreversible, with thinning of the epidermis

***Dermatitis and eczema, including contact dermatitis

Skin and Subcutaneous Tissue Disorders – Frequency not known:

Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules (see section 4.4).

Description of selected adverse reactions

Local effects

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 the risk.

The skin of the face, pilose 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, occur less frequently in adults but may be serious. These effects are most likely to be severe in children.

Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may especially be of importance in long-term treatment.

Growth may be retarded and a Cushingoid state may be produced (symptoms may include moon-face, hirsutism, buffalo hump, flushing, increased bruising, ecchymoses, striae and acne). Benign intracranial hypertension has been less frequently reported.

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 on the skin make very sensitive)
- presence of components or excipients which increase the effect, or the penetration through the stratum corneum.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Reporting can also be done directly to Adcock Ingram Limited at:

Adcock Ingram Limited:

E-mail: Adcock.aereports@adcock.com

Tel: 011 635 0134

4.9 Overdose

See section 4.8

Treatment is symptomatic and supportive. In case of chronic overdosage, symptoms of hypercorticism might occur.

The use of Locoid Crelo® should then be discontinued.

No special procedures or antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.13.4.1 Corticosteroids with or without anti-infective agents.

Pharmacotherapeutic group: Corticosteroid, ATC code: D07AB02

Hydrocortisone 17-butyrate is classified as a potent corticosteroid and after topical administration has a vasoconstrictive, antiphlogistic, antipruritic and antiproliferative action. It inhibits the release of arachidonic acid out of the cell membranes and thus interferes with the initiation of the inflammatory reaction.

5.2 Pharmacokinetic properties

In human *in-vivo* studies, the potency of this form of active ingredient has been shown to be of the same order as other topical corticosteroids classed as potent. The active ingredient metabolises to hydrocortisone and butyric acid.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borage oil

Butylhydroxytoluene

Butyl parahydroxybenzoate

Cetostearyl alcohol

Citric acid, anhydrous

Macrogol (25) cetostearylether

Paraffin, white soft

Paraffin, hard

Propylene glycol

Propyl parahydroxybenzoate

Sodium citrate, anhydrous

Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C. Keep well closed.

6.5 Nature and contents of container

Packed in 30 g and 100 g white plastic bottles with dropper tips and screw caps.

Not all pack sizes are marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

Locoid Crelo®: 34/13.4.1/0221

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/06/2001

10. DATE OF REVISION OF THE TEXT

12 January 2023

Namibia: NS2 05/13.4.1/0427

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