PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

Locoid® Cream 1 mg/ 1 g (cream); Locoid® Lipocream 1 mg/ 1 g (cream); Locoid® Ointment 1 mg/ 1 g (ointment); Locoid® Lotion 1 mg/ 1 g (lotion)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Locoid® Cream

Hydrocortisone 17-butyrate 1 mg per 1 g water soluble cream base

Preservative: propyl parahydroxybenzoate 0,1 % *m/m*, butyl parahydroxybenzoate 0,05 % *m/m*

Locoid® Lipocream

Hydrocortisone 17- butyrate 1 mg per 1 g oil-in-water cream base

Preservative: propyl parahydroxybenzoate 0,05 % *m/m*, benzyl alcohol 0,5 % *m/m*

Locoid® Ointment

Hydrocortisone 17-butyrate 1 mg per 1 g anhydrous ointment base

Locoid® Lotion

Hydrocortisone 17-butyrate 1 mg per 1 mL aqueous solution

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

Lipocream

Ointment

Lotion

Locoid® Cream: A white to practically white cream.

Locoid® Lipocream: A white to practically white cream.

Locoid® Ointment: A white, fatty ointment.

Locoid® Lotion: A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Inflammatory skin conditions e.g., allergy and eczema.

Also suitable for treatment of psoriasis, lichen ruber planus, and intertrigo caused by chemical and/or mechanical irritation.

4.2 Posology and method of administration

Posology

Long term topical use with Locoid® should be avoided, especially in children. Apply the appropriate Locoid® formulation thinly 2 to 4 times daily.

After the initial therapeutic response, application should be reduced to once daily or to 2 to 3 times weekly. The optimal therapeutic effect can only be obtained if the formulation is adapted to the nature of the skin disorder e.g.:

Locoid® Cream has an oil-in-water base with a low fat content

Locoid® Lipocream has an oil-in-water base with a high fat content

Locoid® Ointment has an anhydrous ointment base

Locoid® Lotion has an alcohol-in-water solution base and contains no fat.

Method of administration

For cutaneous use.

Gentle massage may facilitate penetration into the skin. In some cases a better result is achieved with an occlusive dressing.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Do not apply to broken skin.
- Skin infections caused by bacteria, fungi or viruses (for example herpes simplex). Wound treatment especially ulcerous lesions.

- Peri-oral dermatitis.
- History of allergy to the ingredients.
- Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore Locoid®, should not be used during pregnancy.

4.4 Special warnings and precautions for use

Application in or near the eye may lead to glaucoma simplex or subcapsular cataract.

Keep away from the eyes.

Application under occlusion should be restricted to dermatoses involving limited areas.

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

Systemic effects may develop after use for a longer period, under occlusive dressing, intertriginous areas, in a large area of skin and especially in children, leading to suppression of the adrenal cortex function, and can lead to suppression of the growth hormone secretion.

Due to the immunosuppressant and anti-inflammatory effect of corticosteroids, Locoid® may be associated with increased susceptibility to skin infections, aggravation of existing infection, and activation of latent infection. As such, Locoid® 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 (see section 4.3).

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 advise is recommended in these cases or other treatment options should be considered (see section 4.8).

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.

Locoid® lipocream contains benzyl alcohol which may cause mild local irritation.

Locoid® cream contains cetostearyl alcohol which may cause local skin reactions (e.g contact dermatitis).

Locoid® cream and lipocream contains parahydroxybenzoate and may cause allergic reactions which can be delayed.

Instruct patients not to smoke or go near naked flames - 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

Care should be taken in prescribing Locoid® to children.

Locoid® preparations should not be used in nappy areas in infants for flexural eruptions and ideally, should not be used in 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

Corticosteroids such as hydrocortisone pass the placenta and may therefore influence the foetus. This is only of significance when large areas are treated intensively with Locoid®. Corticosteroids

have been shown to be teratogenic in animal studies.

Breastfeeding

Care should be taken when treating breastfeeding mothers with large quantities of Locoid®, as it is not known whether Locoid® absorbed through the skin is present in breast milk.

Locoid® can be used during breastfeeding, but it is recommended to avoid applying Locoid® directly on the breast.

Fertility

No animal or human data on Locoid®and fertility is available.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following side effects are reported less frequently with topical corticosteroids such as Locoid® but may occur more frequently with the use of occlusive dressings.

Tabulated summary of adverse reactions

MedDRA System Organ Class	**Less frequent**	**Unknown frequency**
Immune system disorders		Hypersensitivity

Endocrine disorders	Adrenal suppression	
Eye disorders		Blurred vision*
Skin and subcutaneous tissue disorders	Skin atrophy** Dermatitis*** Telangiectasia Skin striae Purpura Pustular acne Peri-oral dermatitis Skin depigmentation Rosacea-like skin, masking and spreading of infections, steroid acne.	Pruritus Erythema Rash Withdrawal reactions
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).

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 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

Excessive use under occlusive dressings may produce adrenal suppression. No special procedures or antidote.

See sections 4.4 and 4.8.

Treatment is symptomatic and supportive.

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 has a vasoconstrictive, anti-inflammatory, anti-pruritic and anti-proliferative action. It inhibits the release of arachidonic acid out of the cell membranes and thus interferes with the Initiation of the inflammatory reaction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Locoid® Cream:

Butyl parahydroxybenzoate (preservative)

Cetostearyl alcohol

Citric acid, anhydrous

Macrogol 25 cetostearyl ether

Paraffin, light liquid

Propyl parahydroxybenzoate (preservative)

Sodium citrate (anhydrous)

Purified water

White soft paraffin

Locoid® Lipo-cream:

Benzyl alcohol

Cetostearyl alcohol

Citric acid, anhydrous

Macrogol 25 cetostearyl ether

Paraffin, light liquid

Propyl parahydroxybenzoate (preservative)

Sodium citrate (anhydrous)

Purified water

White soft paraffin

Locoid® Ointment:

Polyethylene oleogel (gel of liquid paraffin with 5 % polyethylene)

Locoid® Lotion:

Citric acid, anhydrous

Glycerol (85 %)

Isopropyl alcohol

Povidone K90

Purified water

Sodium citrate, anhydrous

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Locoid® cream; Locoid® lipocream; Locoid® ointment: 36 months

Locoid® lotion: 48 months

6.4 Special precautions for storage

Store at or below 25 °C.

Do not refrigerate or freeze.

6.5 Nature and contents of container

Locoid® Cream: Packed in 15 g coated aluminium membrane tube with a HDPE cap.

Locoid® Lipocream: Packed in 15 g and 30 g coated aluminium membrane tubes with HDPE caps.

Locoid® Ointment: Packed in 15 g coated aluminium membrane tubes with a HDPE cap.

Locoid® Lotion: Packed in polyethylene bottles containing 30 mL or 100 mL. The containers are closed with a white polyethylene screw cap.

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(S)

Locoid® Cream: H/13.4.1/107

Locoid® Lipocream: W/13.4.1/355

Locoid® Ointment: H/13.4.1/109

Locoid® Lotion: H/13.4.1/108

Locoid® Cream: Namibia NS2 90/13.4.1/001377

Locoid® LipoCream: Namibia NS2 05/13.4.1/0428

Locoid® Ointment: Namibia NS2 90/13.4.1/001379

Locoid® Lotion: Namibia NS2 90/13.4.1/001378

Locoid® Lipocream: BOT0200493

Locoid® Lotion: BOT0200508

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 February 1976

10. DATE OF REVISION OF THE TEXT

12 January 2023

adcock ingram

PI 90006349/11-51756401
01/2024