PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

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

Hydrocortisone 17-butyrate

Locoid® Cream contains propyl parahydroxybenzoate 0,1 % *m/m*, butyl parahydroxybenzoate 0,05 % *m/m* as preservative

Locoid® Lipocream contains propyl parahydroxybenzoate 0,05 % *m/m* and benzyl alcohol 0,5 % *m/m* as preservative

Read all of this leaflet carefully before you start using Locoid® Cream, Locoid® Lipocream, Locoid® Ointment, Locoid® Lotion

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse or other healthcare provider.
- Locoid® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Locoid® is and what it is used for
2. What you need to know before you use Locoid®
3. How to use Locoid®
4. Possible side effects
5. How to store Locoid®

6. Contents of the pack and other information

1. What LOCOID® is and what it is used for

Locoid® contains the active substance hydrocortisone butyrate. This is a corticosteroid which when made up as a cream is for use on the skin. This is known as topical application. Locoid® is a potent topical corticosteroid. Topical corticosteroids are able to reduce the inflammation caused by a variety of skin conditions, and so allow it to get better. They can also affect the cause of the condition, which can lead to its healing.

Locoid® is used for: Inflammatory skin conditions e.g., allergy and eczema.
Also suitable for treatment of psoriasis, lichen rubber planus, and intertrigo caused by chemical and/or mechanical irritation.

2. What you need to know before you use LOCOID®

Do not use LOCOID®:

- If you are hypersensitive to hydrocortisone butyrate or to any of the excipients (listed in section 6).
- if the skin is broken.
- to skin infections caused by bacteria, fungi or viruses (for example herpes simplex).
- to wound treatment especially ulcerous lesions.
- if you have peri-oral dermatitis.

Warnings and precautions

Special care should be taken with Locoid®:

- for application in or near the eye may lead to glaucoma simplex (pressure in the eye).
- facial and genital skin, rectal mucosa and intertriginous areas are extra sensitive to Locoid®; adaptation of the dosage may be necessary.
- for use on an area where you have previously had a skin infection.

- for psoriasis. Topical corticosteroids can be effective in psoriasis in the short term. The condition may relapse or significantly worsen on stopping treatment and there is a risk of widespread pustular psoriasis. This is a condition where the psoriasis spreads and becomes very inflamed. In order to minimise side effects Locoid® Cream should only be used on small areas of psoriasis (e.g., scalp, hands and feet). If your doctor has prescribed Locoid® Cream to treat psoriasis, you should let your doctor review your progress regularly as such treatment needs careful supervision.
- if there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within days to weeks, do not restart using the cream/ointment without consulting your prescriber unless your prescriber has previously advised you to so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

During treatment:

Contact your doctor if you experience blurred vision or other visual disturbances. If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within days to weeks, do not restart using the cream/ointment without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience burning sensation, please seek medical advice before restarting treatment.

Do not 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.

Children

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.

Other medicines and Locoid®

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using Locoid®.

Hydrocortisone, as contained in Locoid® passes the placenta and may therefore affect the foetus. This is of significance when large areas are treated intensively with Locoid®. Corticosteroids have been shown to be teratogenic in animal studies. 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.

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

Driving and using machines

It is not always possible to predict to what extent Locoid® may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which Locoid® affects you.

Locoid® Cream and Locoid® Lipocream contains cetostearyl alcohol, propyl parahydroxybenzoate, butyl parahydroxybenzoate and benzyl alcohol

Locoid® Cream and Locoid® Lipocream contains propyl parahydroxybenzoate and butyl parahydroxybenzoate that may cause allergic reactions (possibly delayed).

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).

3. How to use Locoid®

Do not share medicines prescribed for you with others.

Always use Locoid® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Gentle massage may facilitate penetration into the skin.

In some cases a better result is achieved with an occlusive dressing.

After the initial therapeutic response, application should be reduced to once daily or to 2 to 3 times weekly.

The doctor will decide on which Locoid® formulation is suitable for your condition.

If you have the impression that the effect of Locoid® is too strong or too weak, tell your doctor or pharmacist.

If you use more Locoid® than you should

See possible side effects. Treatment is symptomatic and supportive.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Locoid®

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

Locoid® can have side effects.

Not all side effects reported for Locoid® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Locoid®, please consult your healthcare provider for advice.

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.

If any of the following happens, stop using Locoid®and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if your skin condition seems to get worse, the skin becomes red, itchy or irritated
- if Locoid® is used in moist skin areas (e.g. skin folds) the skin may become thin and damaged.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- adrenal suppression (inability of the adrenal gland to release hormones in response to stress)
- thinning of the skin (atrophy), often irreversible
- redness of the skin (dermatitis)
- stretch marks
- spider veins
- a rash of purple spots due to small blood vessels leaking blood into the skin, joints, intestines or
- organs

- pustular acne
- redness of the skin around the mouth (perioral dermatitis)
- discolouration of skin
- blushing face with often small, red, pus-filled bumps on the face
- steroid acne
- worsening of the skin condition during treatment (Bounce-back effect)

Side effects with unknown frequency:

- blurred vision
- itching (pruritus)
- redness of the skin (erythema)
- Steroid withdrawal reaction:

  If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.
- application site pain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Locoid®.

5. How to store Locoid®

Store all medicines out of reach of children.

Store at or below 25 °C. Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Locoid® contains

The active substance is hydrocortisone butyrate. Locoid® contains 0,1 % hydrocortisone butyrate.

The other ingredients are:

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 and white soft paraffin.

Locoid® Lipocream: Benzyl alcohol, cetostearyl alcohol, citric acid, anhydrous, macrogol 25 cetostearyl ether, paraffin, light liquid, propyl parahydroxybenzoate (preservative), sodium citrate (anhydrous), purified water and white soft paraffin.

Locoid® Ointment: Polyethylene oleogel (gel of liquid paraffin with 5 % polyethylene)

Locoid® Ointment: Citric acid, anhydrous, glycerol (85 %), isopropyl alcohol, povidone K90, purified water and sodium citrate, anhydrous.

What Locoid® looks like and contents of the pack

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.

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 tube with a 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.

Holder of Certificate of Registration

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene, Pretoria

Tel: 012 345 1747

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Locoid® Lotion: H/13.4.1/108

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LOCOID®
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05/13.4.1/0428

LOCOID® Ointment: 90/13.4.1/001379 LOCOID® Lotion: 90/13.4.1/001378

BOTSWANA: S2 LOCOID® Lipocream®: BOT0200493 LOCOID® Lotion: BOT0200508

Access to the corresponding Professional Information

An electronic copy of the Professional Information (PI) is available on the Equity website

http://www.equitypharmaceuticals.co.za or http://www.sahpra.org.za.

An electronic copy of the Translated Patient Information Leaflet (PIL) is available on the Equity website

http://www.equitypharmaceuticals.co.za