PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

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

Contains propyl parahydroxybenoate 0,3 % *m/m*, butyl hyroxybenzoate 0,15 % *m/m* as preservatives.

Contains butylated hydroxytoluene 0,02 % *m/m* as anti-oxidant

Read all of this leaflet carefully before you start using Locoid Crelo®

- 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 Crelo® 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 Crelo® is and what it is used for

Locoid Crelo® contains the active substance hydrocortisone butyrate. This is a corticosteroid which when made up as an emulsion is for use on the skin. This is known as topical application. Locoid Crelo® is classed as potent corticosteroids. 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 Crelo®:

- if you are allergic to hydrocortisone butyrate or any of the other ingredients of this medicine (listed in section 6).
- if you have 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)
- if you have ulcerous skin lesions, wounds and broken skin
- if you have adverse reactions induced by corticosteroids (e.g. dermatitis perioralis, striae, atrophicae)
- if you have Ichthyosis, juvenile dermatosis plantaris, acne vulgaris, acne rosacea, fragility of the skin vessels, skin atrophy
- the use of this product is not recommended in children under 2 years.

Warnings and precautions

Special care should be taken with Locoid Crelo®:

- If you treat facial skin, thin skin (e.g. skin of your genitals). These areas of your skin are particularly sensitive to corticosteroids. You should not apply to your eyes or your eyelids.

- If you use Locoid Crelo® at skin folds, under an airtight dressing or on large areas of your skin. If you are using Locoid Crelo® under bandages, it should only be on small areas for a short time, and only on the advice of your doctor.
- if you use it on an area where you have previously had a skin infection.
- if you use it 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 Crelo® should only be used on small areas of psoriasis (e.g. scalp, hands and feet). If your doctor has prescribed Locoid Crelo® to treat psoriasis, you should let your doctor review your progress regularly as such treatment needs careful supervision.

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 Crelo® should not be used during pregnancy. The use of Locoid Crelo® is not recommended during lactation (see section "pregnancy, breastfeeding and fertility" below).

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 Locoid Crelo® 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 a 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

The use of this product is not recommended in children under 2 years (see section "Do not use Locoid Crelo®").

Locoid Crelo® should not be used in the nappy areas on babies or children.

Other medicines and Locoid Crelo®

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

Pregnancy and breastfeeding

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 Crelo®.

Locoid Crelo® should not be used during pregnancy.

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

Driving and using machines

It is not always possible to predict to what extent Locoid Crelo® 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 Crelo® affects you.

Locoid Crelo ® contains propyl parahydroxybenzoate, butyl hydroxybenzoate, butylhydroxytoluene and propylene glycol.

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

Locoid Crelo® contains butylhydroxytoluene may cause irritation to the eyes and mucous membranes (e.g., nose).

The propylene glycol may cause skin irritation.

3. How to use Locoid Crelo®

Do not share medicines prescribed for you with others.

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

Locoid Crelo® is for cutaneous use.

Long term topical use of corticosteroids should be avoided especially in children. Apply 1 to 3 times daily a small amount of Locoid Crelo® onto the skin. 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.

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 an occlusive dressing.

If you use more Locoid Crelo® 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 Crelo®

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

4. Possible side effects

Locoid Crelo® can have side effects.

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

If any of the following happens, stop using Locoid Crelo® 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 Crelo® is used in moist skin areas (e.g. skin folds) the skin may become skin atrophy) and damaged, often irreversible.

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:

- 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 *

- thinning of the skin (atrophy)
- redness of the skin (dermatitis
- spider veins (telangiectasia)
- stretch marks (striae)
- bruising (ecchymosis)
- a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura)
- redness of the skin around the mouth (perioral dermatitis)
- acne
- discolouration of skin (depigmentaion)
- excessive hair growth anywhere on the body (hypertrichosis)
- blushing face with often small, red, pus-filled bumps on the face – Rosacea-like dermatitis
- worsening of the skin condition during treatment (rebound 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

* 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.

* 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.

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 Crelo®.

5. How to store Locoid Crelo®

Store at or below 25 °C. Keep well closed. Store all medicines out of reach of children.

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 Crelo® contains

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

The other ingredients are borage oil, butylhydroxytoluene, butyl parahydroxybenzoate, cetostearyl alcohol,

citric acid, anhydrous, macrogol 25 cetostearyl ether, paraffin; white soft, paraffin; hard, propylene glycol, propyl parahydroxybenzoate, sodium citrate, anhydrous and water.

What Locoid Crelo® looks like and contents of the pack

Locoid Crelo®: A white to practically white emulsion.

Locoid Crelo®: Packed in 30 g and 100 g white plastic bottles with dropper tips and screw caps.

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 Crelo®: 34/13.4.1/0221

NAMIBIA: NS2

LOCOID® Crelo:
05/13.4.1/0427

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