

Package leaflet: Information for the user

Locoid Crelo®

Hydrocortisone butyrate 0.1% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Locoid Crelo is and what it is used for
2. What you need to know before you use Locoid Crelo
3. How to use Locoid Crelo
4. Possible side effects
5. How to store Locoid Crelo
6. Contents of the pack and other information

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. Corticosteroid creams, ointments and other topical preparations come in four different strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent corticosteroid has a much stronger effect than a mild corticosteroid. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Locoid Crelo is classed as moderately potent corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition. 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 Crelo is indicated in adults, children and infants above 3 months of age. It is used to treat a variety of skin conditions which are not caused by micro-organisms especially those affecting the scalp, hairy or facial skin, such as eczema and dermatitis (itching) of all types including atopic (childhood) eczema, photodermatitis (itching caused by exposure to light) and dermatitis caused by skin irritants and allergies.

It can also be used in the treatment of psoriasis, a condition resulting in thickening of areas of the skin. It is important that you follow your doctor's instructions particularly in psoriasis, and use it only on small areas on the scalp, hands or feet. The original symptoms may return if you stop using Locoid Crelo prematurely.

2. What you need to know before you use Locoid Crelo

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), and see also the end of this section for some important information on some of the ingredients.
- if your skin disorder is caused by an untreated **bacterial, viral (e.g. cold sores, herpes, chicken pox), fungal (e.g. athlete's foot), yeast or parasitic (e.g. ringworm) infection**. Locoid Crelo may worsen or hide these disorders. Your doctor will check these.
- if you have skin problems associated with **syphilis (a sexually transmitted disease) or tuberculosis**.
- if the **skin around your mouth is inflamed (perioral dermatitis)**. It might be the result of previous treatment with corticosteroids.
- if you have **pimples or spots (acne)**.
- if you have **redness of the facial skin**.

Warnings and precautions

Talk to your doctor before using Locoid Crelo. This is especially important if you intend to:

- 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.
- 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. Bandages and dressings should not be used on babies or children.
- treat your child (see further information below).
- 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.
- use it on an area where you have previously had a skin infection.

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 2 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 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 and adolescents

Long term treatment of children should be avoided. In infants treatment should be limited to a maximum of seven days. Bandages and dressings should not be used on babies or children.

Other medicines and Locoid Crelo

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

You should not use Locoid Crelo if you are pregnant or breast-feeding unless clearly necessary. There may be a small risk of harm to your baby if you use any corticosteroid emulsion whilst pregnant, so if your doctor does prescribe it for you knowing you are pregnant, you should not use it in large amounts for a long time.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Locoid Crelo is unlikely to affect your ability to drive or use machines.

Locoid Crelo contains cetostearyl alcohol, butylhydroxytoluene, propylene glycol, propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate

Locoid Crelo contains cetostearyl alcohol and butylhydroxytoluene that may cause local skin reactions (e.g. contact dermatitis).

It also contains propylene glycol which may cause skin irritation. The butylhydroxytoluene may cause irritation to the eyes and mucous membranes (e.g. nose). The propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

3. How to use Locoid Crelo

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure. If your skin problem does not improve, you should go back to your doctor.

The recommended dose of Locoid Crelo is no more than twice daily. Thickened areas of psoriasis on elbows and knees may be treated with Locoid Crelo under a dressing, but only if your doctor has told you so.

This medicine is for cutaneous use. Apply a thin layer of Locoid Crelo to the affected skin. Gently massage the emulsion into the affected area.

On advice of your doctor you may have to apply Locoid Crelo under an airtight dressing in order to obtain a better result.

Unless you are using Locoid to treat your hands, always wash your hands after using Locoid Crelo.

If you use more Locoid Crelo than you should

If you have used too much Locoid Crelo the side effects (as described in Section 4) can occur. Contact your doctor, pharmacist or nurse immediately.

If you forget to use Locoid Crelo

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

If you stop using Locoid Crelo

The original symptoms may return if you stop using Locoid Crelo prematurely.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A small number of people may be hypersensitive (allergic) to the constituents of Locoid Crelo. If your skin condition seems to get worse, the skin becomes red, itchy or irritated, tell your doctor, pharmacist or nurse if this becomes troublesome.

If Locoid Crelo is used in moist skin areas (e.g. skin folds) the skin may become thin and damaged. Tell your doctor if this happens.

Locoid Crelo may cause the following:

Rare side effects (may affect up to 1 in 1,000 people)

- Thinning of the skin (atrophy)
- Redness of the skin (dermatitis)
- Bruising
- Stretch marks
- Facial spots (acne)
- Redness of the skin around the mouth (perioral dermatitis)
- Worsening of the skin condition during treatment (Bounce-back effect)
- Discolouration of skin

Very rare side effects (may affect up to 1 in 10,000 people)

- Suppression of the release of the stress hormones

Frequency not known (cannot be estimated from the available data)

- Allergic reaction (hypersensitivity)
- Blurred vision
- Itching (pruritus)
- Redness of the skin (erythema)
- Rash
- Application site pain
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after 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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Locoid Crelo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original packaging. Do not refrigerate or freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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 macrogol 25 cetostearyl ether, cetostearyl alcohol, white soft paraffin, hard paraffin, borage oil, butylhydroxytoluene (E321), propylene glycol (E1520), sodium citrate (E331), citric acid (E330), propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate and purified water.

What Locoid Crelo looks like and contents of the pack

Locoid Crelo is a white emulsion and is available in 15 g, 25 g, 30 g, 50 g or 100 g tubes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Neon Healthcare Ltd.
8 The Chase, John Tate Road,
Hertford,
SG13 7NN
United Kingdom

Manufacturer:

Temmler Italia S.r.l.,
Via Delle Industrie 2, 20061, Carugate (MI), Italy

Further support and information for skin conditions such as eczema can be gained from:

National Eczema Society
11 Murray Street, London
NW1 9RE, UK.
Helpline Tel: 0800 089 1122

This leaflet was last revised in November 2023